UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC WORKSHOP - PRIORITIZING NUCLEAR MATERIALS REGULATORY APPLICATIONS FOR RISK-INFORMED APPROACHES

Embassy Suites Hotel
Chevy Chase Rooms 1 and 2
4300 Military Road, NW
Washington, DC 20015
Wednesday, April 26, 2000

The above-entitled workshop commenced, pursuant to notice, at 8:40 a.m.

PARTICIPANTS:
F.X. CAMERON, FACILITATOR
ROBERT BERNERO
ROY BROWN
CHIA CHEN
ORMAN EISENBERG
JOHN FLACK

JONATHAN FORTKAMP

BARBARA HAMRICK

PARTICIPANTS: [Continued]

GARY HOLAHAN

RAYMOND JOHNSON

JOHN KARHNAK

FELIX KILLAR

ROBERT LULL

STACY ROSENBERG

MARTIN VIRGILIO

ANDREW WALLO

MICHAEL WANGLER

P R O C E E D I N G S

[8:40 a.m.]

MR. CAMERON: Good morning, everybody. We still have a couple people out standing around the table, but we'll get started and let them pick up with us as we come in.

I have some suggestions on how we might proceed this morning for your consideration, and these suggestions flow out of a summary that I did of the notes from yesterday. I think everybody has a copy of this and what I would suggest is that we sort of do a reprise of yesterday's discussion on safety goal, which I think was really a good discussion, and do that by giving you an opportunity to comment on the points that were brought up yesterday and to put a finer point on them, if you need to.

I'm not sure that I captured everything correctly for you. So we'll give you an opportunity to do that.

At 9:15, and these times are obviously approximate, as you can tell from yesterday's session, but we sort of moved into -- from some of the general conceptual, philosophical points about safety goals, we started to move into actually taking a look at the feasibility of developing safety goals for particular

categories of materials used.

I would also thank Dennis yesterday for his comment that you will see on these notes about the fact that who is the target population that's being protected by the safety goal in each of these categories and are they -- and what are the implications of whether it's a voluntary or involuntary risk.

I thought that perhaps our main startup discussion might be to look at the various categories, and we also had a discussion about there's plenty of values submerged already in the existing regulatory framework. Why don't we go through category by category and talk about, well, what are the values submerged in that framework that might contribute to the development of a safety goal, do we already have a safety goal perhaps in any category, what's the feasibility of developing a goal. So that would be one major discussion.

After the break, I think I've asked Norman Eisenberg, who is teaching a course on risk assessment, to just give us a short overview of the tools involved in this. We talked about tools yesterday in the safety goal discussion, but I think it might be useful for people to have an understanding of what those tools are, to bring more

information to the decision-making process and to allow people to make a clear separation, in their mind, between the use of the tools and the development of the safety goals, and which Gary Holahan clearly brought home to us yesterday is as an exposition of what the underlying social values might be in a particular regulatory area.

We need to have a discussion of process issues; in other words, where should the NRC go from here to further develop these goals, including -- I don't want to forget a point that was brought up yesterday about what's the organizational framework that the NRC is going to use to proceed here. I think there was a comment about how is the NRC organized to further pursue this effort, and Marty may have some thoughts about that.

I also want to give everybody around the table an opportunity, and in the audience, to sum up their views. I don't mean to take a long time with each person, but based on what you have heard over the past day and a half, to give us your perspectives again on risk.

We will adjourn at noon on the dot, because people have other venues that they have to get to.

Comments on these suggestions in terms of a way to proceed. John?

MR. FLACK: Whether the development of the safety goal should be considered or performed or done in a relative sense to other risks or in an absolute sense. I think that's the question that still remains.

MR. CAMERON: Yes. And let's save that to when we go into these points and we'll go back to you first on that. I just want to make sure that everybody is fairly comfortable with this way of proceeding. And if we need to make a little detour along the way, that's fine, too. All right.

Well, let's go through the points. Everybody should have a handout and I saw, I think, Cindy came in, there is a handout of these points right here. Do you have one? You've got one. All right.

John, you offer your -- why don't you offer your point now and we'll try to capture that.

MR. FLACK: Well, in light of the development of safety goals for reactors, the goal itself recognized risks in general due to power production and used that going in; that everyone is exposed to a certain risk and that we would formulate the safety goals in light of that, in a relative sense, rather than in an absolute sense, where we have, as we have today, certain requirements that are transformed

into millirem, so many millirem as a requirement that we need to meet, which is an absolute number.

I'm wondering if we can somehow decide whether or not these goals for materials would be developed the same way as reactors, and that would be that it would be considered -- the safety would be -- the risk would be considered in light of risks that individuals are normally exposed to, whether it be occupational or public risk from other sources.

That was the intent of the comment.

MR. CAMERON: Let me go first to Gary on that point.

MR. HOLAHAN: The first thing I'd like to say is I liked it better yesterday, where we could speak out.

With respect to John's comments about relative versus absolute goals, it seems to me that in the reactor area, the safety goal expresses both, an expression that the risk to people in the vicinity of the nuclear power plant should be very low, and I think there is a second goal that says that the risks should be comparable to or less than alternative methods of producing electric power.

So in that sense, the reactor safety goals have both an absolute expression and a relative expression. If

you think about it a while, I think you probably have to have both somewhere, because if there was an alternative way of generating electricity or of looking for cracks in the pipe or for whatever purpose you use materials, if there was an alternative way of doing that, that had much less risk to society, I think you would always -- you would favor such a thing, and to have a goal that doesn't recognize that I think is not realistic.

MR. CAMERON: Andy, do you have a comment on that, also? Let's go to you and then we'll go to Bob Bernero.

MR. WALLO: I kind of agree with what Gary said. I think this ties, though, to your very first bullet that you should have qualitative safety goals and clearly qualitative generally implies some relative metric or measure.

I think you suggested we were going to go through some categories and look at them and I think the answer to this question is going to be tied to those categories, because I think in each unique situation, you might find that your safety goals, other than some generic safety goal, like Gary mentioned, that whatever you're doing has to be comparable or better than your alternatives, in general, I mean, that's a great motherhood type goal and something that

actually you should do in a decision-making process.

But the fact is depending on what you're doing, there are those things you may be doing this process for, where you're doing it for many operations, you're going to have many sealed sources out there and you're going to set goals for managing many sealed sources.

On the other hand, you're going to deal with maybe only one repository for high level waste in the whole history of this country. I mean, that's a possibility. Well only ever have one repository.

Do we need absolute goals? Probably not. Probably what we need, we don't even need a -- maybe we don't even need a regulation. What we need is a decision-making process that goes through and says is this the best alternative we have, can we do something better, what's the relative comparison between this alternative versus others and if we don't do this, are we going to have a marked improvement in safety or in whatever else we want.

So I think part of the answer to John's question is tied to what it is you're trying to regulate or improve safety on. In those unique situations, you probably don't want absolute. You want a comparative program rather than a set of standards that you apply, like you would for sealed

sources, where you're dealing with hundreds to thousands of them.

MR. CAMERON: Thanks, Andy. Bob, if you could make your comment and, also, if you have anything to add about what Andy said, too.

MR. BERNERO: It's in the same vein. What I was suggesting yesterday about qualitative safety goals I would like to repeat and in this context, especially what Andy was just saying about the high level waste repository, there is a unique difference between the qualitative safety goal that one would associate with a waste disposal site, with a fissile material handling site, with a sealed source, with the various elements of NRC/NMSS oversight.

I did a little bit of noodling and I would suggest at least five categories of qualitative safety goals and they would be like what the reactor safety goal is, the risk shall be low compared to other methods or, alternatively, the risk shall be low relative to the background risk of everyday life.

So there should be, first, a qualitative statement of risk objective or risk management objective and then one can -- just as in the repository, I suggested yesterday, no person in future will suffer an exposure we wouldn't find

acceptable today for permitting or licensing. That's a goal, that's an objective.

One can then say I will feel satisfied that if I have analyzed to a period of 10,000 years using the performance models and this dose assessment point, presuming there will be somebody there 10,000 years from now and taking due account of uncertainties that, by best expectation, is no person receiving something I wouldn't permit and would do sensitivity analysis to my uncertainties, that even if I'm wrong, the result is tolerable. It's not the edge of the cliff that everybody dies.

So those are implementing quantitative details, just as one-tenth of one percent of background accident risk and cancer fatality risk is an implementing set of details.

So I think I'd be happy to go through those suggested goals, if you wish, now or later.

MR. CAMERON: Can we -- is it more appropriate perhaps in terms of our discussion of when we get to category by category?

MR. BERNERO: Well, I put them together as just categories.

MR. CAMERON: Why don't we start off the category

discussion with your overview on that, and we can move through these points and get the reprise done here.

Felix, you have a comment on this issue we're talking about?

MR. KILLAR: Yes. I think one of the things you have to look at is you've got to have a combination of factors. I think you have to have qualitative, quantitative, you have to take into consideration perceptions. It's not a simple thing and I think as we've been talking for the last day, it's obvious it's not a simple thing.

If you have too qualitative, then you get too much concerned with the perception of risk and you don't get to actually understand what the true risk is. On the other side of the coin, if you get hung up on the true risk or the quantitative risk, then you lose the qualitative aspect of it.

So you have to have a proper blending of these and the blending has to be appropriate for the categories. So I think the idea of having it by categories makes a lot of sense.

One of the things, you talked a little bit about what Dennis suggested yesterday. I agree with Dennis for

all of his audience, except he's left one audience out, and that is the patient, the nuclear medicine patient.

When you talk about the risk to the patient, there's a lot of difference in the risk to the public or to the physician or to the technician or to the supplier. The patient has a lot of different priorities than all those others.

So when you start looking at that, and nuclear medicine is one of those unique categories, where that guy wants that radiation, please, give it to me, versus somebody else who is trying to be concerned and trying to keep away from it.

So you've got to take that aspect into consideration, as well, when we talk about who the affected audiences are.

MR. CAMERON: Thank you. We'll get into another discussion of those issues. Mike, on this issue?

MR. WANGLER: Yes.

MR. CAMERON: All right.

MR. WANGLER: Just a couple of thoughts on it. It strikes me that a qualitative goal is an effective way to try to achieve something that you want. You have a qualitative goal, then you've got to have some sort of way

to measure whether you've achieved that goal and you get into quantitative measurements.

One of the things I've always been struck by is that if you set yourself up for a quantitative goal or quantitative achievement, if you have to change the quantity, you've now got to change your goal, whereas if you have a qualitative goal, you can constantly reassess how to achieve that goal with your quantitative measurements and adjust them as appropriate.

For example, worker radiation levels. The occupational exposure periodically changes, depending on what the international and national communities have. If you set that exposure level as your goal, then you have to change the goal periodically, depending on what the international community says.

MR. CAMERON: Any comments on what Mike just said about that? Bob?

MR. BERNERO: That's the very reason I think you ought to start with a qualitative goal and that's an implementing detail that if we decide, like ICRP-60, that five rem per year is not approved, worker exposure, that we ought to go to some ten-year average and whatever, that's an implementing detail.

But the safety goal, qualitative safety goal should describe why a worker exposure is acceptable, the goal is acceptable at a substantially higher level than public exposure.

MR. CAMERON: Okay. Great. I think we've captured those there and let's make sure everybody is comfortable with some of these statements. The first bullet is obviously qualitative safety goals. Then we have the issue of quantitative goal. I think we've been covering these; whether qualitative or quantitative, the underlying rationale for the goal should be explicit and clear as to what and whose values it represents.

And if anybody wants to make a point on any of these, just flag me down here. Safety goal is only one value to be used in decision-making; agency must also consider what Gary termed the hidden values in terms of society expectations.

I guess I had a question about that. Are those -- should those hidden values be exposed in terms of setting the overall goal? Gary, do you want to comment on that.

MR. HOLAHAN: My comment is yes.

MR. CAMERON: So let's make a note on that one. That's a clarification.

MR. EISENBERG: Chip?

MR. CAMERON: Yes. Norman?

MR. EISENBERG: On this particular point, some of the framework is not very hidden. In fact, it's very explicit, and it's very important on the materials area, Federal radiation guidance, just all kinds of overall requirements, impact of what the goals, what the quantitative goals, if there ever are any, what those are going to be.

I think it's important to somehow tie that in, because it's a significant and important constraint on what gets done in the materials area.

MR. CAMERON: Does anybody have a comment on what Norman just said? Chia, do you have a comment on this?

MR. CHEN: Yes. We should say that a safety goal is to be used in decision-making and then a later part of those things such as social expectation. I think those should improve in the description of the goal.

MR. CAMERON: Does anybody have a disagreement with that?

MR. WALLO: I have a question here.

MR. CAMERON: All right.

MR. WALLO: I'm not quite understanding. The

discussion doesn't seem to follow the text of the one. The impression I got from the discussion, the exchange here, was that the safety goal needs to consider and maybe develop along the lines considering these other attributes, these hidden values.

The way this is phrased, it sounds like you're going to set the safety goal and then you also have to consider the hidden values.

MR. CAMERON: That's why I asked Gary for a clarification on that. So that phrase, that point should be amended so that it doesn't give the impression that you set this goal and then there's all these other hidden values that might influence what you do; that those hidden values should be exposed as part of developing the safety goal.

So that particular phrase should be or that point should be amended. That gives a wrong impression. Okay.

MR. WALLO: I guess the other thing I would comment on that, I don't like the term hidden value necessarily, but all these other attributes that go into making a safety goal, an individual goal can't necessarily take into account every attribute.

You may have several goals, some of them specifically designed to address one or more of these

attributes in your decision-making process.

So I want to make sure that not every safety goal has to consider every hidden value. On the other hand, hopefully you're suite of safety goals that you decide to evaluate your system on will ultimately address all the attributes you need to address.

MR. CAMERON: I think that the term hidden value is a good term to use to try to really emphasize what the conceptual importance is in terms of a safety goal. It's important from that standpoint, but I think that that's sort of a transition term and there may be a better term to use than hidden value.

I think I see people around the table agreeing that they don't like hidden value. But I think in the way that Gary used it, it was very educational and instructive to really emphasize what is involved in developing a safety goal.

So I think from now on, we can perhaps refer to attribute. Is that acceptable to everybody? All right. Well, go ahead. John, you have a comment on this?

KARHNAK: Yes. I guess maybe I don't understand the definition of hidden value, because I'm not sure that anything is hidden there. I think these other values or

other attributes are things that should be considered and to suggest they're hidden somehow puts some magic to them I don't think exists.

MR. CAMERON: And I think I'll let Gary finish us off on this one, since he started it.

MR. HOLAHAN: I guess since I introduced the term. What I meant by it is not that people are hiding these, but that they have not been articulated directly. That they are values that people have and they have not directly played out in the process.

For example --

MR. KARHNAK: But I think they have. I think we heard a lot of them yesterday.

MR. HOLAHAN: But I don't think you will see them expressed directly. For example, that you ought to have different levels of protection for voluntary versus involuntary activities I think is a social value, but I don't think you'll see that written down in the regulations somewhere.

You may see it expressed in the numbers that worker exposures can be different from public exposures, but the thought that you're doing that for this reason I don't think you'll find written down. That's the only thing I

meant, in the context that it's not fully articulated.

MR. CAMERON: And I think that that's probably it, is if you look at a particular regulation, if these particular values wouldn't be necessarily explicitly articulated, but they are very important to consider in developing a safety goal, then they do have to be explicitly articulated.

Bob?

MR. BERNERO: I'd just like to make a point on what Gary just said, which is the distinction between public exposure limits and worker exposure limits, I don't think it's proven to associate it simply with voluntary and involuntary. The real reason for it is not voluntary and involuntary so much as I think it is a matter of assurance and control that you have health control of the worker and you have very close monitoring and control of the rate of exposure and the extent of exposure.

MR. CAMERON: And let's also bring that back in to when we get to the category by category discussion. Bob?

MR. LULL: I know we're trying to be more general in our terminology, but it seems to me that the really only worse thing in using the term safety goal, what we mean by that is radiation exposure.

I mean, whether those safety goals are that the NRC is inherently interested in and other than radiation exposure to people, we're only interested in the environment insofar as it will eventually potentially lead to radiation exposure of people.

And so I'm interested in what other safety goals are we talking about and are there any other hidden values other than just this concept of voluntary or involuntary. Are we going to take into account people's misperception of radiation risk and include that and really botch things up?

MR. CAMERON: Gary, I think I'd like to hear your thoughts on that.

MR. HOLAHAN: At first, I thought I agreed with you, that, in fact, almost all of what we do simply has to do with separating people from radiation, whether it's controlling the radiation or keeping people away from it.

But it occurred to me that I think George Apostolakis, who is on our Advisory Committee on Reactor Safeguards, raised an issue and it was discussed at a number of our meetings, and that is when he was doing some work for the State of California, the issue came up about whether land contamination was, in fact, a separate issue.

If you could do an analysis that basically said no

one will be affected by this radiation, is it acceptable to put a level of radiation in a water supply or on the ground of people are not going to be exposed? Is there an environmental issue separate from a people and radiation exposure issue?

The answer in California was yes. Now, the NRC doesn't have land contamination goals, although protecting people from radiation, in fact, provides a certain level of protection in that area.

In my mind, this is just one of those value questions. We ought to decide whether contaminating land in a way that has no effect on people or no calculable effect on people is an important value or not. You could probably argue over that and then you'd decide yes or no, but at least it gets that issue on the table.

MR. LULL: May I respond to that? I think --

MR. CAMERON: Can people here back there? The microphones are not up as loud as they were yesterday.

MR. LULL: I'll try and speak closer into it.

MR. CAMERON: We may need to try to get someone to adjust our mixer back there.

MR. LULL: I think the point that you're addressing is important and it really goes to the fact that

people don't believe that you can ever say that land may not at some point in time be occupied by people; that if you have something into the environment, eventually, sometime in the future, if it's a long-lived isotope, that it can end up coming in contact with people and creating a significant exposure potentially.

So that there is no way of contaminating the land or the environment or the water and saying that that's never going to come in contact with people. It restricts the land in a way that no one has the power in the future to control for certain, and that's what they're looking for is certainty.

MR. CAMERON: I just would call your attention, on this subject, a point Norman raised yesterday about applying the tools on the risk triplet, the consequences portion of the triplet. Norman suggested that a comprehensive, a broad look at the consequences portion may help to identify the values that underlie the safety goal for a particular area.

Norman, I know you want to comment on this, so why don't you go ahead. Not on this statement necessarily, but on this discussion.

MR. EISENBERG: There is another aspect. There is a lot of discussion here about the qualitative safety goals,

what the intent is, and the quantitative safety goals in terms of what risk level is to be achieved. Unfortunately, risk is not a universally and well defined term and if you're trying to reach a particular goal, you have to recognize that another aspect of the analysis and the compliance of demonstration is going to be what confidence do you have in achieving the goal.

And I think perhaps some thought should be given by the NRC to including some qualitative and perhaps quantitative statements regarding confidence in achieving a particular risk level in the articulation of the safety goal.

And in the materials area, it can become especially important. Let's just think about -- and some of these examples have come up already. Let's just think about, say, a risk goal that's stated in terms of the normal dose that would be acceptable to a member of the public.

If you demand a 99.9 percent demonstration that that level will be achieved, it may drive you to very restrictive kinds of requirements for releases or for the other aspects of the system which will be out of proportion to the risk that is likely to actually be experienced.

I think this is an aspect of the safety goal which

probably needs to have some attention, because just a statement of risk objectives, especially in the materials area, may not essentially solve the problem, may not be a good representation of what the society really wants.

MR. CAMERON: I think that this is -- we're going to hear more of this from Bob when he goes through his five levels. I think that he was trying to incorporate how you deal with uncertainty, perhaps confidence levels. And I guess confidence levels may relate to how perception is factored in.

I just would point out that we had some discussion yesterday about public perception may be reflected in the underlying social values represented in a safety goal. This reflection would not necessarily be consistent with the scientific consensus.

Gary, I don't know if you want to put a finer point on that. I think it might be real useful to talk about that a little bit.

MR. HOLAHAN: I was thinking about something like this on the way home yesterday, and I'm not an expert on this subject, but I will use it as an example anyway.

The law for food additives and those sorts of things, which I think some people here probably understand

better than I do, include something that's called a Delaney Clause, which basically says you're not allowed to add to foods any material that's a known carcinogen at any level. So it's basically a zero tolerance approach.

I think the scientific community would say, well, you know that there are natural carcinogens in foods, there are all sorts of reasons to say that you could establish a non-zero standard that was negligible or ten percent or a thousandth of a percent of the natural risk with respect to foods.

But the Congress put that in there and I think the scientific community would say they didn't need to do that. It's done as a public confidence sort of thing and it seems to me it's been there something like 25 years and Congress is a group that's rather responsive to what the public wants.

The public hasn't thrown any of the Congress out on that point. There's been no clamor to say, no, you're restricting my food supply in an inappropriate way.

So I think that's a case in which irrational, is the public being irrational? Well, I think the scientific community would say this is not the optimum solution. This is not producing the optimum safest food supply, but it

seems to me what the public wants. And in a democratic process, it's what has come out of that process and I think it will probably stay there so long as that's what the public understands that they want.

I think that's an example of this kind of thing.

MR. CAMERON: Can we get some -- does anybody else have anything to say on this important issue of how public perception is built into the development of safety goal? Barbara, you had your card up. You took it down when Gary was talking, because --

MS. HAMRICK: It was to respond to something Gary had said earlier.

MR. CAMERON: Okay. Mike, perception issue?

MR. WANGLER: Well, let me address the perception issue in a broader term. What I fear we're forgetting about here is if we look at the chart over here and we look at the bullets you have up here, what I fear that we're losing sight of is that development of a safety goal is a process.

We're looking at individual elements, but it's a process. You have your goal, you generally define your objectives to meet the goal, and then you have an implementing plan to meet your objectives and achieve your goal.

As part of that process, I would think that one would have to look for the, quote-unquote, hidden values, involve public participation, so you can get as much information as you can in order to develop your safety goal.

The development of a safety goal can't be a BOGSAT, a term in DOT when I was there, a bunch of guys and gals sitting around a table just deciding what needs to be done.

MR. CAMERON: What was that DOE term?

MR. WANGLER: DOT term, B-O-G-S-A-T, BOGSAT, a bunch of guys sitting around a table.

MR. CAMERON: Okay. I never heard that one before.

MR. WANGLER: It's a Garfield one. It's supposed to be the result of a process where you get as much input, information as you can, and then arrive at the development of a goal in the best way you can.

MR. CAMERON: We always wondered how DOT arrived at some of those things.

MR. WANGLER: That's how they make SWAGS.

MR. CAMERON: SWAGS, yes. That's the term I learned from Bob Bernero a long time ago. But you're raising a very important point, a way to expose perceptions,

values, is we have to remember that the process for development of safety goal has to be an inclusive process of all of the interests that may be affected by that particular area.

Ray?

MR. JOHNSON: I'd like to speak to the matter of perceptions and also conservatism. What I see happening when it comes to implementing safety goals is that we talk about the public having perceptions which are hard to understand technically or scientifically, but I would suggest that technical people have perceptions also which affect how they implement guidelines or requirements.

For example, the cleanup criteria for contaminated lands, the 15 millirem EPA number and 25 millirem NRC number, when it comes to implementing such guidelines, my suggestion is that those who are doing the implementing are going to go for zero, because that's the only way they can be sure they're going to meet either guideline.

Consequently, both those numbers are the same in terms of how they become implemented. So we can have all the debate about what's the difference and which is more conservative and all that, but when it comes to the real world of implementation, they're both the same. To assure

meeting them, the people who are responsible are going to go for cleanup and if they can find an atom of measurable activity, they're going to remove it, and that's what is happening.

So it's conservatism on the part of those who are responsible for implementing programs to be sure that they meet the goals or the guidelines.

MR. CAMERON: Tying that back into what Mike said and some of our previous discussion is that I would imagine in terms of developing a safety goal, that one of the affected interests obviously is the licensee community and questions of implementation would be grist for the mill, so to speak, wouldn't it, in developing that goal? Issues such as that.

Bob, do you have a quick comment here?

MR. BERNERO: Just a quick comment on that particular thing. When you go into the implementation of, say, a soil decontamination standard, there is a valuable resource out there, the MARSSIM manual, which was jointly prepared by DOE, NRC and EPA, and it doesn't really go to zero, but it does establish that whatever your threshold, your goal or your criterion is, you can have substantial confidence that you're not there, but below it, and there is

an inherent conservatism to it, but that is a very complicated process.

MR. CAMERON: Okay. What I would like to do is take the remaining cards and see if there's any other comments on some of these points and make sure that we ask the audience before we move on whether there's any comments out there.

John, let's go to you first? You had your card up.

MR. FLACK: I guess my comment is directed to the last two speakers about what we mean by a goal. I always envision a goal is something that you try to achieve, but it wasn't a requirement that you had to achieve it.

But what it does even quantitatively, it's not a number where we have to meet it with some confidence, but it's a number that expresses what we expect or try to achieve, and we work towards that and that begins to drive things a certain way.

But it's not a requirement that you need to be meet it and wouldn't be unacceptable if you didn't. It's just that this is something we'd like to aspire to.

So in that context, I think at least my -- that's how I envision development.

MR. CAMERON: Let me go to Gary now on that point or whatever else you wanted to raise.

MR. HOLAHAN: Actually, since I thought you were going to close out your summary here pretty soon, I wanted to comment on the last dot on the first page.

MR. CAMERON: Okay. And that's in the materials area, safety goals should focus on accidents, particularly the impact on workers.

MR. HOLAHAN: Yes.

MR. CAMERON: I think this came from Bob yesterday and I don't know if I captured it correctly. Go ahead, Gary.

MR. HOLAHAN: Well, I guess it's the one I didn't agree with.

MR. CAMERON: Okay.

MR. HOLAHAN: I think the safety goal should broadly consider all the categories and all the sources of risks and all the targets or whatever you wanted to call them.

I think it certainly should include accidents and workers, but I think just the way it's written here, it looks like it's calling for a focus or an emphasis on one over other issues.

I wouldn't think that you'd want to do that.

MR. CAMERON: That's a good point. I'll let Bob talk to that. I characterized it as in terms of being all inclusive and I don't know if you meant it that way. Go ahead.

MR. BERNERO: Yes. Actually, it's a matter of emphasis or focus. It is theoretically true that off-site risk to the public as well as worker risk should be considered. But in the point I was trying to make, in the majority of material facilities, there is no mechanism to provide or to cause significant off-site risk.

Note, for instance, the Tokimora accidental criticality did irradiate people off-site, but it's from an extremely small site in a congested area. The point is in the U.S. material facilities and large facilities in particular, the emphasis needs to be on worker risk and it is showing up in the regulations that worker risks are the stated objectives, as well as public risk.

I don't deny the public risk, but it's just that the emphasis ends up being on worker risk because of the risk profile of the NMSS facilities.

MR. CAMERON: I guess that may be a good example of what needs to be considered in developing a goal and it

ties us back into the perception issue. In the development of a goal, you need to look -- and perhaps when we go through category by category, some of the statements will be offered that, for example, a facility such as a Japanese facility, when you look at what the risk is off-site, it's very small.

MR. BERNERO: But perhaps a better comparison that I should have used instead of the Japanese facility is in material facilities regulated under 10 CFR 30 and its companion regulations, where sometimes the worker is a radiation worker and there is an RSO, radiation safety officer, providing some kind of oversight and control, and in other cases, the worker is not, you know, with a gauge, for instance.

You have a sealed source in a gauge in some industrial process and you are focusing on worker safety with perhaps a different standard than you would have for a technician in nuclear medicine, who isn't really a radiation worker.

MR. CAMERON: Let me ask Gary, from his experience in terms of developing a safety goal. We've talked about in terms of risk assessment methodologies, one of the things that are identified there, you identify pathways,

probabilities, et cetera, et cetera.

How is all of that factored into the goal in relationship to the social values? I mean, how is all that packaged together, Gary?

MR. HOLAHAN: I'm not sure I can answer that question, but I can at least respond to Bob's comments. What Bob said is technically correct. I think the risks are generally focused around the workers. But I don't think that would change the way I would write the safety goals.

It seems to me the safety goals are written for the public or the patient or the worker, for children, for adults, whatever. Then you may find that, in fact, few, if any requirements are needed to protect the public in certain cases and a lot of requirements are needed to protect the worker. But I still think you start out with a broad set of goals, that when you come down to the level of what's required to meet those goals, you may find that that's where you have to focus the requirements and the constraints.

MR. CAMERON: Bob, do you agree with that?

MR. BERNERO: Not entirely, because I think that doesn't recognize the fact that the nuclear material is placed within the biosphere, within the public, and it is not always managed with radiation workers. It's a very

profound difference between reactor regulation and material regulation.

The material is deliberately placed in the biosphere in use, for some use, and so you -- yes, indeed, you do have to have a safety goal for the public and you do have to have a safety goal for the radiation worker, but you must take into account this blend between a radiation worker on a site and someone working near or around or with a nuclear material source of some kind.

I think this can come out in the formulation of safety goals.

MR. CAMERON: In the process.

MR. BERNERO: Yes.

MR. CAMERON: Well, what I would like to do is to go with -- we'll start with Chia Chen and we'll take these cards and then come back over to Gary. Then I want to see if anybody out there in the audience has a comment. Chia Chen, go ahead.

MR. CHEN: I'd like to make two comments. First is about the risk. There is no zero risk and when Gary and Ray say we have it crossed off, that means we don't talk about zero risk, so that's one thing.

Second is in the goal and in order to take care of

the hiding value and some other thing, I think after the general statement of the goal, maybe at the end, we should say that this is to ensure that there is no health impairment to the workers, general population, and long-term damage to the environment.

MR. CAMERON: Okay. Anybody else? Let's go to Bob Lull.

MR. LULL: My comments are related to the concept that when we're talking about dealing with public perception, we have to realize that the public is defined by activist groups, like Judith perhaps, they won't accept anything that increases their risk of cancer, and that's what we're talking about.

We're talking about additional theoretical risk of cancer from radiation exposure that you calculate. You're setting like a maximum. You're saying, okay, our goal is you're going to have no more than this much additional exposure. Well, there's a sizeable and very vocally active part of the public that says I don't want to have any increase to what I'm already facing in life and I don't want you guys, who are doing this for your profit or because you're part of this industry group, to increase my risk of cancer from this radiation, a deadly radiation exposure.

I would think that perhaps everywhere where we use the word risk, we add the word -- I know it's redundant, but we add the word theoretical risk, because this is basically theoretical. You know, what happens at the kind of radiation exposure levels we're talking about is hypothetical, theoretical, and there is no real good data, which is why it's so argued. People can say, well, I think it's above linear or below linear and people argue about this and there is no real consensus either within the scientific community or within the regulatory community.

We're using linear extrapolations because that's safe side and has been used throughout our history and we buy into that, but that's a hypothesis. That's not absolutely driven by strong data that's totally convincing.

There are people thinking that hormesis plays a role. If that were true, that would have a profound impact on everything we're talking about. So the science that's going into and evaluating that is getting a better handle on risk at these levels will be very important.

I would think that where we use the word risk, however, to emphasize the fact that it is theoretical, that we ought to use the term theoretical risk, just like some of

the public uses the term deadly radiation as a linked phrase. I think that we cannot emphasize that sufficiently, that we're talking about hypothetical, theoretical risks in all of these goals that we're setting and that might help you eventually in a process of educating the public, which is going to be a long-term, very expensive process, but that's eventually what's going to need to happen if we're ever going to get beyond this impasse.

MR. CAMERON: Gary, do you have any thoughts on what Bob just said?

MR. HOLAHAN: Yes. I agree with some of the elements of his comments, but I don't think they belong in the safety goal. If I go back and think about Mike's comment earlier about changing standards and things, I think you want your safety goal to be a reflection of real safety and real risks and then at some lower level you say the best science available today says this is the theory or this is the effect and to deal with that at a lower level.

I wouldn't put the word theoretical in my safety goal, because I think you're trying to protect real people from real risks. Then at a lower level, you say the best science we have today says this is how we should do that and let that evolve with the science, and if there is a better

theory than linear, then fine, then you put that in. But I don't think it should change your goals.

MR. LULL: The point is that when you say real risks, that at these levels, they aren't real risks. They're theoretical risks. So it just feeds this whole thing.

I have one other comment and I think in terms of you included patients for safety goals and while, in certain circumstances, that's true, I think you need to be aware that the patient is very different from the public in any other way and that the benefits and risks are balanced by the medical decisions and that really needs to remain a medical decision.

MR. CAMERON: Thank you, Bob. Let's go to Marty.

MR. VIRGILIO: Just my summary comments on our discussion and this section. If I look across what we wrote down and how we've modified it today, the one thing that strikes me, taking in the discussion as well, is we tend to be narrowly focused at this point on the public health and safety and the worker.

But I look across the responsibilities that our office has in NMSS, and we spoke to them a little bit yesterday in the seven program areas, and you can cut it

seven ways or four ways, as we did in the Commission paper, but we also have responsibilities for protecting the environment and we also have responsibilities for safeguards, sabotage, theft and diversion of materials.

I think we need to be broad in our thinking as we take the next step in this process about all those responsibilities and an appropriate set of goals that will address that full range of activities that we have to deal with.

MR. CAMERON: Good point. And when we start our discussion of category by category or activity by activity, let's not lose sight of those two important areas of interest.

Felix?

MR. KILLAR: I couldn't have said it better than what Marty said it. In fact, I should have introduced this yesterday and I left it out and so I'm going to take the opportunity to introduce it today.

The NRC, in NUREG 1614, their strategic plan, they have already defined a strategic goal for nuclear material safety, and that's to prevent radiation-related death and illness, promote the common defense of security, protect the environment and use of source byproduct and special nuclear

material.

They go on to articulate these and say that no deaths resulting from acute radiation exposure from civilian use of source byproduct or special nuclear materials or death from other hazard materials used or produced from licensed material, go on to say no more than six events per year resulting in significant radiation or hazardous material exposures from the loss or use of source, special nuclear material and byproduct material.

Go on, no events resulting in release of radioactive material resulting in civilian use of source, byproducts, special nuclear materials that cause an adverse impact on the environment.

Then they go on, no loss, thefts or diversions of former quantities of nuclear material, radiological sabotage, unauthorized enrichment of special nuclear material regulated by the NRC. And then the final one is no unauthorized disclosure or compromise of classified information causing death -- or damage, excuse me, to national security -- death, damage.

The NRC has already articulated the safety goals. They already have it in their strategic plan. So to me, what we should be focused on is they've done it, they've

done the work, how do we implement these, unless we have real problems with these. And from what I've seen in the discussion the last two days, these seem to pretty well lay out what we've been talking about.

MR. CAMERON: Let me ask a very important question. What is the -- have, indeed, the safety goals been set by the Commission in the strategic plan? What's the relation between the strategic plan and the development of safety goals in the materials area? Are we just talking about implementation? Are we talking about sub-goals? Did the strategic plan, if it was labeled as development of safety goals, would there have been more interest in terms of the public -- and I'm using that term broadly -- participation in the development of those safety goals?

What are some thoughts on that? John, you had your card up on this.

MR. FLACK: I visualize the strategic plan as strategic goals. That's why you see zeros. You could meet these strategic goals, but you may not meet your safety goals, because safety goals involve probabilities and risks, which you're constantly exposed to.

So you may not, for example, have a core melt, you may have zero core melts, and you would say, well, have you

met your safety goal, you may not have met your safety goal because the risks that you expose the public to may have been unacceptable, although you just happen not to have a core melt.

So I think we have to be careful in defining what we mean by strategic goals which are in this plan and safety goals which we want to aspire to, which involves exposing the public to risk, whether or not you have an accident. So it's more forward-looking.

But I do agree that the implementation of those strategic plans need to be laid out and I believe that's where we're moving with the risk-informed regulation implementation plan, which then defines how these strategic goals would be reached through some implementation of risk within the regulatory process.

So those two need to be fit together, but I don't, at least myself personally, I don't see that as a safety goal itself. I see these as strategic goals. These are the things we want to have happen, but safety goals involves probabilities and risks of exposure, both accidental and occupational.

MR. KILLAR: Well, I've got a real problem, because I don't understand the difference between the two,

because, to me, a strategic goal and a safety goal should be one and the same and that you certainly recognize that a goal is a goal and that the probabilities that occur that you can exceed that goal, you want to minimize the possibility of exceeding that goal, but there is a probability you can exceed that goal.

So if you had a strategic goal, that strategic goal can be the safety goal as well. Just as they indicated here, no deaths from acute radiation, that certainly is a goal, but that can happen. Tokimora is one example of where that happened. Certainly that was a goal in Japan as well.

MR. FLACK: I look at one as being a deterministic goal and one as a probabilistic goal and I think that's where maybe we're trying to combine the two into one goal, and I see them as two different pieces. I don't see them as one and the same.

MR. CAMERON: Let me interrupt this exchange to perhaps ask Joe Murphy, from the reactor area, how do you -- how do you address this relationship between safety goal and the goal set out in the strategic plan? A hypothetical question is if we went up to the Commission and said that, well, we don't need to develop any safety goals because indeed you have already done that, what would be the

Commission reaction to that? Joe?

MR. MURPHY: I suspect that in the reactor area, it's a lot easier just because of the timing. The reactor safety goal has been in existence since '86 and the strategic plan came later.

The strategic plan has numbers, it has the same sort of numbers and zero deaths, but we know that the risk is not expressed in -- the risk is not zero. But within the time period that the strategic plan is addressing, which ties back to the Government Performance and Results Act, zero is a good number, if you want a number, but, in fact, we know the risk is not zero.

I don't know whether that answers the question, but what I see in the case of NMSS, you do have an advantage that you have just recently set these strategic plans and now you have to ask yourself are these the appropriate safety goals; is your goal really zero or the numbers.

One advantage in the materials performance goals is there are numbers other than zero. There are numbers that have derived from data and these may well translate into goals that you're trying to meet.

I think John made an important point earlier in the meeting, where he said a safety goal is something you

strive for. It's something that you try to be at, but it is not what we call a definition of adequate protection. You can live in an area higher than the safety goals, without regulatory concern, but you will look at it always from an ALARA standpoint or a cost-benefit standpoint to see does it make sense to drive the risk lower.

I think with the reactor end, because the safety goals came first, we didn't have that problem, but I think you have a tremendous leg to build on in the strategic -- the performance goals, I guess they are, in the materials area, forgetting the ones that say zero, unless that is really your goal from a risk standpoint.

But as I go and look at the performance goals, there are real numbers that derive from data. They seem to express exactly where you want to be and those may be directly comparable.

I think you have to take each one one at a time and look at it and see where you want to go with it.

MR. CAMERON: Thanks, Joe. Felix, thank you for raising this issue, because I think it's a real important one to consider as we move forward.

Let's go to Roy and then we're going to move down the line here. Roy?

MR. BROWN: Kind of a follow-up to Bob's comments earlier, and then Bob Lull, also. Bob mentioned that on the materials side, you actually have materials out in the biosphere, you're introducing them into the biosphere, and that's absolutely correct.

That's where the benefit comes from, actually using these unsealed sources and injecting them into patients.

What becomes important is the use of barriers and barriers was discussed at length in SECY paper 99-062, where they introduced the concept of barriers and said that the barriers have to enter into the equation.

In this case, the barriers would be things like packaging, the transportation, training of the nuclear medicine technologist, all those things need to enter into the safety equation, too, and those need to be considered, as well.

So I think that's very important.

Also, I wanted to comment on something Bob Lull said earlier about risk to the patients, and I want to absolutely reiterate what Bob was saying. Patient, safety of the patients is not a concern of the NRC. That's why the FDA licenses radio pharmaceuticals. That's why we have

boards of medicine, boards of pharmacy, and it's the physician's discretion of risk versus benefit for the patient and it's really out of the NRC's jurisdiction.

So I just wanted to amplify that.

MR. CAMERON: And I think, Roy, I would like you to bring that up when we get to the discussion of the specific areas, the specific categories. I think that's a really relevant point in terms of development of safety goal in the use of radio isotopes in the medical area.

Let's go to Norman and then to Jonathan.

MR. EISENBERG: I have what I hope are three quick points. With regard to worker risk in the safety goal don't whether or not it should be the focus, first, in the waste area, I disagree with Mr. Bernero. I think that there worker risk is probably not the focus. It's mainly public risk.

Second, I think in the spirit of the safety goal, it's probably better to set up the goals for all the risk receptors, if you will, and then if it turns out that some risks are unimportant, as evidenced by experience or analysis, then so be it. Then you don't have to worry about those things.

I think it may be true that in the facility

operations or the operating aspects of what NMSS has oversight over, the worker risks probably are the dominant risks in terms of the magnitude of the risks.

But I think that doesn't mean that you should have that influence what the safety goals are, because safety goals, I think, should be comprehensive.

The third point, regarding this strategic goal versus safety goal, perhaps one way to look at it is with regard to the point that I brought up before in terms of confidence. If the goal is zero death from exposure to radiation, one could achieve that by merely shutting down all activities involving radioactive material.

That means that the tolerance for achieving that goal is very high. Whereas if you state an objective in terms of a risk goal, it says, well, our goal is no deaths, but we will accept a certain small probability that that will occur, and it's useful to state explicitly what that probability is.

MR. CAMERON: So that the strategic goal is even a sort of a higher level, idealistic objective, in your mind.

MR. EISENBERG: I think it's more than idealistic, but it's a high level goal and I think the safety goals are a means to implement a program so that you achieve that

goal, considering the practicalities of the ability to implement economics and other societal factors.

MR. CAMERON: Gary.

MR. HOLAHAN: On that last point, I agree more with Joe Murphy's expression of the relationship between strategic and safety goals. I would consider the safety goals higher level, more general, long-term goals, and the strategic goals are an expression of what you're trying to achieve this year or in the next five years or something like that.

That's why numbers like zero show up, because, in fact, you want to achieve zero deaths. But in the longer term, you recognize that the risks aren't zero.

So maybe this is just terminology, but it seems to me that the safety goals are the higher level goals.

But the other point, I don't think the strategic goals, as they are now, can serve the purpose of safety goals, because right now, they're only an expression of NRC's goals and they haven't been laid out to be tested to see whether, in fact, they are the public's goals.

I think if you were to go through -- if you wanted the strategic goals to serve that purpose, then I think you would put them on the table, put them out for workshops,

public comments and all those sorts of things, and then include those thoughts into some revision of the strategic goals.

But I suspect that there's still a more general expression than what do we expect this year.

MR. CAMERON: Perhaps the strategic goals really need to be looked at in the context in which they were developed relative to the Government Performance and Results Act, and perhaps looking at a shorter term or a planning context rather than a longer term context that you would get into when you set a safety goal, and also remember Gary's very important point, I think, on process.

It's that I don't know if any one of us would argue that the development of the strategic goals, although there was public input, was the type of process that would be necessary to set the safety goals, which would be the public goals, as Gary has termed it.

MR. HOLAHAN: Can I just finish that thought?

MR. CAMERON: Yes, go ahead.

MR. HOLAHAN: I think the strategic goal document might very well be a good place to articulate the safety goals, because I don't think you want safety goals in one document, strategic goals in another document, without a

clear understanding of how they relate to each other.

So I can very well imagine that there is one document that has both of these discussions in them at some point.

MR. KILLAR: That was the point I was going to raise. They're two separate ones, because as a member of the staff, which one do they follow? They say, well, I'm going to follow this one today and I'm going to follow that one tomorrow.

MR. CAMERON: Well, I think that you need to, at the very minimum, the strategic plan should explain the relationship between the strategic goals and the strategic plan and whatever safety goals were developed, and not only should they both be in there, but the relationship should be explained.

I think what Gary and others are saying is that the strategic goals are not equivalent, at least at this point, are not equivalent to what we're terming safety goals.

But this whole area of discussion has to be more carefully explored, I think, and it's a question of the NRC undertakes all these various different initiatives and it's left to sort of later on to connect the dots between them.

I want to get Jonathan on and then I want to ask anybody in the audience whether they have a comment. Jonathan, you've waited patiently for a long time.

MR. FORTKAMP: Throughout this discussion, what we're doing is constantly moving toward lower and lower standards. It seems like everything we're bringing up is pushing the standards low, and I think it's important to remember that a lot of the material licensees, as Dr. Lull mentioned, very minimal doses.

I mean, many of these licensees, if you look at just radiation doses to the workers and certainly to the public from those activities, you're bouncing around background.

I think what I would like to see considered in development of these safety goals is also the work licensees are doing and not to go so low that you're inhibiting their ability to use the nuclear materials for their activities.

Again, I think it's especially important when you're bouncing around zero doses to workers and to members of the public.

MR. CAMERON: Thank you, Jonathan. Andy, final comment up here.

MR. WALLO: Yes. I wanted to comment, to Dr.

Lull's comment, that we're dealing only with exposures in safety and I think that was adequately addressed, and I strongly disagree that exposure is the only issue there. There are many other factors you need to consider in setting your safety goals.

But the other thing is would agree, although Bob's comment that, yes, probably, as things now stand, workers and accidents are major issues, you can't set a safety goal centered around them because then the response will be, well, the easiest way to protect workers, for instance, is I could discharge everything in the river and put the burden on the public.

The integrated safety management system, which was one of the approaches you're looking at, says I evaluate the hazards, I identify the hazards, I evaluate the risks, I take some mitigation steps, then I re-evaluate. If indeed you go through that process with your safety goal and say I've got to mitigate some risks to workers, you do that, your re-evaluation said, uh-oh, I'm transferring these risks to the public, then you have to correct that.

That process has to involve both the public and the workers and those other things besides exposure. As a matter of fact, in Norman's comment that waste disposal is

largely public, not worker risk, I guess I would say waste disposal is largely hypothetical risk.

Even in those instances where waste disposal has failed drastically, there's not been any cases of real exposures. The impact of failed waste disposal objectives has been cost. We spend a lot of money.

So the ultimate issue in waste disposal is long-term integrity to minimize costs to society, and so that may be another thing, is that you're not necessarily eliminating an exposure either of the worker or the public, but you're designing a facility that will have minimal maintenance costs for the future and thereby minimize the impact on society from a cost standpoint.

MR. CAMERON: Thanks, Andy. And we really need to close this off and get going, so just real quick, Mike, and we'll let Bob say something quickly here.

MR. WANGLER: I guess I'm conflicted a little bit about the definition of goal, and maybe I'm getting hung up on goal. I'm sorry, I'm trying to use the mic.

I'm conflicted a little bit about the use of the term goal, because I've heard several different uses. John has mentioned a goal is something you try to achieve and you set up your process to constantly evaluate where you are in

achieving that goal. Once you achieve the goal, then you have to develop a new goal because you're there.

On the other hand, Andy just talked about the integrated safety management system, where you have an overall goal and you have, I guess, various facilities trying to achieve that goal, some of which can do it with their system, others which take a lot of effort to arrive where they want to be.

I guess the one thing I wanted to ask Gary about is I heard Joe say that there's been a reactor safety goal since '86 and I guess I would like to kind of find out which definition or how that goal is considered, whether the goal is an end point or whether it's something that's going to be continually strived for into perpetuity.

MR. HOLAHAN: You're correct. The safety goal was written in 1986, but then a lot of these discussions of exactly what is the goal and how does it work were continued after that. It was a 1990 expression by the Commission that the goal is, in fact, something that the Commission wished to strive for, and I think it is a continuing thing.

But the idea of striving for it doesn't -- in my mind, it's not a one-sided thing. In other words, when you're striving for that goal, you may find that you're

over-achieving it and, therefore, you're doing too much or you might find that you're not doing enough.

So there's some course correction involved. It doesn't always mean that I'd like to be able to do the mile run faster and faster and faster. It's not that kind of goal. It's a sort of optimal goal. If I achieve this level of safety, this is the appropriate level, and if you find that you're doing too much, then, in fact, perhaps you should do less, because if you're doing too much with respect to your goal, you are wasting money or you are diverting resources or you are over-valuing something with respect to what's proper and you're probably causing some more harm in some other arena.

But I think that the safety goal is this sort of something to strive for through your regulatory programs and it's an optimization sort of thing.

MR. CAMERON: Bob, did you want to say something?

MR. LULL: Yes, maybe a clarification. As I see it, the NRC is basically not concerned about explosions or acid exposure or toxins other than radiation. Now, that will be part of operational goal-setting and strategies, particularly in terms of the reactor environment.

But in terms of what we're talking about here,

that's not the appropriate -- because there are other agencies that control these things. And when you talk about radiation exposure, you're basically talking about people's fear of getting cancer from getting exposed to radiation, whether it be the public, the worker, or even the patient, exposure of the patient, although that's something that's taken elsewhere into account.

I don't think anything that I've heard -- everything boils still down to the potential of someone getting that exposure and, therefore, having a risk of getting cancer, and I know that you disagree and I would be interested in anything that you -- in a safety issue that's --

MR. WALLO: If the issue was just to limit exposures, for instance, the Commission might say, well, doctors or radiation workers, when they're doing treatment, so let's suit them out in lead outfits to make sure they don't get any irradiation. That would be nonsense.

MR. LULL: I'm not saying the goal should be zero. I'm saying that that's the concern.

MR. WALLO: You can't get down to zero with a lead outfit, but you can reduce it.

MR. LULL: Doctors do wear lead outfits when they

are exposed.

MR. WALLO: If it was just exposure that you were concerned about --

MR. LULL: They have sufficient lead, that's why they do it, because they're concerned about just the exposure. What else are they concerned about?

MR. WALLO: They're concerned about being able to treat the patient. They're not going to suit the doctor. I can make a remedial action worker go out in a full respirator suit and I get accidents out the kazoo. I do serious damage to the workers, I get heat exhaustion, I don't write a regulation to limit exposure. I write a regulation for integrating safety management.

MR. LULL: I understand what you're saying. What you're saying is you don't want to interfere with the functions that people are trying to achieve with the -- I wasn't addressing the optimization thing, but what I was addressing is that the risk that is of concern is the radiation exposure causing cancer.

MR. WALLO: And the second risk is that to the environment itself. There is concern that protection of humans does not protect the environment.

MR. LULL: I understand that.

MR. WALLO: So we have standards for environmental protection, too.

MR. LULL: But that has to do with perhaps property rights, but also eventually with the fact that some human can get exposed to that at some point.

MR. WALLO: No, no, it doesn't. It has nothing to do with human exposure. It has to do with the current requirements and maybe the NRC doesn't have this charge, but I think they do. We, as the Department of Energy, have to be stewards of the natural resource by laws written by Congress.

So when we write our regulations and our requirements, we have to make sure that they address cultural resources, natural resources, and the environment.

Now, we don't, hopefully, sacrifice humans for some of these, but on the other hand, there has to be a balancing. We can't take an action that would destroy an ecosystem. We can't take an action that would destroy a national cultural resource.

Our safety guidelines have to balance all those.

MR. LULL: But those are other issues other than NRC. It's not an NRC issue, per se. NRC's control of radiation and radiation in the environment.

MR. WALLOW: We have legislative mandates that take us right there in protecting the environment, particularly in uranium recovery issues. There are a broad range of issues outside of your scope.

MR. LULL: I'll stop, but all those things were driven by the potential risk to people eventually interacting with the environment and while the --

MR. CAMERON: I want to hear a final comment from Barbara on this.

MS. HAMRICK: I just wanted to say that it's not driven by exposure to people. We deal with a lot of issues in our branch that are strictly ecological issues, exposure to plant life, exposure to the desert tortoise, exposure to different species, and we deal with that. We interact with Fish and Game, the U.S. Fish and Wildlife.

We're dealing with BLM on some issues, ecological exposure on the land. So the concern is not just exposure to people. There is a lot of effort in the area of ecological exposure.

MR. CAMERON: For example, those are social values as expressed in certain statutes, such as endangered species.

Let's move right into the categories. We had

asked Bob Bernero to sort of give us the take on five safety goals. You go ahead and start.

MR. BERNERO: Basically, what I was noodling is the possibility of starting with qualitative statements of goals parsed not only by areas of regulation for NMSS, but by the aspects of regulation such as chronic exposure, accident risk, and so on.

And what I did is I just laid out five, with the possibility of an additional one, in the following sequence. The first one I chose was waste disposal, and this is all waste disposal, not just the high level waste or low level waste, decommissioning, so forth. I said yesterday what I think is the obvious safety goal for that, that no one in future will receive an exposure we wouldn't find acceptable today. It's a projected exposure.

And then there still remains a very complex consideration of how do you decide that that is adequately achieved, because you can't go out and measure it.

Then one also needs, in waste disposal, to address the mechanics of handling the waste. There are clearly safety requirements associated with packaging, handling, if it's shallow land burial, the opening of trenches and so forth, and there are aspects of safety, radiation safety,

ALARA, the quality of operations or safety of operations that people don't get squashed on, industrial safety, and sometimes even process safety, because there are waste incinerators, super compactors, waste processing steps associated with that.

Those are areas that need a safety goal, like there would be a standard sort of a safety goal, is what is the goal in radiation protection of a radiation worker, and then later on, in another category, you would have ALARA or chronic exposure to worker, goals that would be for workers who aren't, quote, radiation worker, unquote.

So the waste disposal would have the two categories. One is the overall objective of the waste disposal and, secondly, what are the intermediate goals for management of the process.

The second category I chose was casks or packages, containers. Typically, often not welded shut. So distinct from sealed sources. These are casks or packages for transport and one has to have a statement of objective for chronic exposure. In this case, both for the workers handling or monitoring, like dry cask storage, you have people going out there and looking at it, surveying it, checking the temperature, making sure that squirrels and

leaves haven't clogged up the cooling passages.

But you also have the chronic exposure risk to the public and that's -- yesterday we heard a lot of those are real people at the road side and real estate that purportedly is devalued because there's some radioactive material going to go down the pike. And that chronic exposure to the risk needs explicit -- chronic exposure to the public needs some explicit statement of objective.

What is the Commission trying to achieve? Negligible, very low? One needs some kind of qualitative statement so that an implementation can be achieved. If you've ever worked with the big type packages, the shielding for casks is such that a potentially significant scenario is the thing is sitting in a railroad yard and a hobo or wanderer chooses it as a place to sleep.

They're not zero dose casks. So some qualitative objective needs to be stated for that.

And then accident consequence and the accident consequence has to address how robust this package must be with respect to whether or not foreseeable accidents can result in a serious local hazard.

In other words, after the accident, you've got a real mess and possibly an irretrievable mess. We used to

speculate about the scenario on spent fuel shipping casks, that you pop the lid off when the collision occurred and you spilled all the spent fuel assemblies onto pavement, breaking some of them in the process.

That would be very difficult to clean up. That would be a great local hazard, but that's not even close. To implement satisfactory shipping standards under Part 71, you aren't even close to something like that.

And so the accident consequence qualitatively stated. Part 71 is loaded with A-2 quantities and everything like that, how do you analyze acceptable robustness, but you need to have a qualitative statement of the safety goal for that.

Then a third category is sealed sources. Here, the chronic exposure safety goal is one that very frequently involves uncontrolled exposure; that is, outside of the RSO jurisdiction. It often does have RSOs, but you often have stuff that -- you know, like radiographers, there are chronic issues.

So you need a qualitative goal for the chronic exposure and you need an accident goal. Now, 10 CFR 30 something, I can't remember the citation, but there is, for sealed sources, there is a standard of robustness that I

can't remember the details of, but it's buried in one of the 10 CFR 30's. It's basically how robust is the sealed source lest you have an accident shearing, a spilling or something like that.

But what you need for a qualitative safety goal is what is the objective, how robust, in qualitative terms, should the Commission want to make it.

Along with that, on the sealed source, the Commission should also have a qualitative objective of the risk associated with loss or abandonment. Now, I'm sure some of the people in this room are aware of the gauges that occasionally get lost and they end up in scrap and they go through a smelter of scrap metal and the cesium or whatever it is ends up in the bag house dust.

So you have health consequences or environmental contamination that can result from loss or abandonment. Some of you may recall Boyani of Brazil about ten years ago, where a teletherapy source was abandoned and some salvage guy got it and broke it open a little girl coated herself with cesium-137 chloride, and it was horrible. I forget. I think the little girl died and that's an abandoned source.

There are other examples, Cobalt-60 sources have been lost, the Mexican table legs that got picked up here in

the states. That was about 20 years ago.

So there should be a qualitative statement of risk expectation associated with loss or abandonment of these sources.

Then I had a potential sub-category. There's a whole category of unsealed sources. Most of the unsealed sources, in my recollection, are radio pharmaceuticals; that is, in quantity. Those, I think, could be handled separately. But there are a lot of unsealed sources that, for instance, 10 CFR 40.22 has been a nagging regulation for a long time because it gives a general license to go get many, many, many pounds of uranium every year for research, development and filling sand bags or whatever you're going to do with it.

And I can't remember his name, but there was a radiological vandal who went from state to state out in the west, working on the 40.22 license, and I don't know if he was ever brought to ground, but it's an unsealed source and it's regulated without control.

It's a general license. So there needs to be some statement associated with unsealed sources and there, too, the abandonment.

Now, whether or not you count static eliminators

as unsealed sources, you go back '88, I think it was, that there was a polonium-210 static eliminator design that was based on microspheres or polonium-210 for static eliminators, but blow air across it, the alpha ionizes the air.

The only thing wrong was the QA system broke down on the cement and people were sweeping up polonium beads all over the place. So you have -- those were distributed under general license. You have to have an underlying objective, which is what risks or what level of protection does the Commission expect for the use of such sources.

And those are technically unsealed sources.

MR. KILLAR: Bob, on those unsealed sources, what do you do as far as the unsealed sources that are used for tracers in environmental studies and research and things along that line? Do you include them in this category?

MR. BERNERO: You would go into categories. The 40.22 is the extreme at one end, massive amounts of uranium. At the other end are the tritium, carbon-14, and so forth, where the shear quantity is so small that you get into how many dead cats you can put in a landfill or something, but --

MR. CAMERON: Stop right there, no talk about dead

cats. What I would like to do, Bob, is get your whole taxonomy.

MR. BERNERO: There are just two more.

MR. CAMERON: And then see whether it's acceptable to use this taxonomy for discussion purposes.

MR. BERNERO: Two more categories. Category four is medicine, nuclear medicine. That would include therapy or diagnosis. Chronic exposure for a doctor, worker, but not the patient, accident exposure and here you get into a very sticky area of jurisdiction.

The NRC for years has edged over the jurisdiction into patient safety. The Indiana-Pennsylvania incident as an example, and prior to that, the so-called misadministration rule, where back in the '80s, the NRC developed and promulgated a rule about if you give the wrong dose, do you have to tell somebody and what are the controls on telling somebody. It's really patient safety and equity.

And so accident or mishap, it would be useful to have a statement of that. Once again, loss or abandonment is an aspect in nuclear medicine, because that does happen.

MR. LULL: Radiation therapy.

MR. BERNERO: Yes.

MR. LULL: It's an important distinction between

nuclear medicine and radiation therapy. I don't they should be lumped.

MR. CAMERON: I don't think we're picking this up for the transcript. We will come back to visit these areas.

MR. BERNERO: Then the last category, five, is large process facilities. I am trying to embrace here where a nuclear material is in large quantity and it's being processed or handled in some way and whether it's a uranium mill or enrichment plant or a fuel fabrication plant.

And the qualitative safety goals needed are, once again, the chronic exposure, which is both on-site and off-site, as Gary noted. Yes, you've got to consider that. And for fissile material facilities, you have a whole category of nuclear criticality safety goals, both prevention and the goals for reaction and response.

So it would be a qualitative statement of the degree of prevention or avoidance of accidental criticality and the degree of reaction or response capability.

MR. CAMERON: Is that mitigation?

MR. BERNERO: Yes. You get into questions of mitigation in the emergency. For example, Tokimora kept going and how do you shut it off.

MR. CAMERON: Right.

MR. BERNERO: And then the other category which is true for all of them is process safety. Process safety is the usual code word for chemical safety or steam, other hazardous aspects of the process, and that, too, has what degree of prevention and what degree of reaction or response is appropriate.

And with the chemical involved in some facilities, you could have very significant off-site response.

MR. CAMERON: Is this another one that is a jurisdictional issue?

MR. BERNERO: Yes. This is the one where you really have a jurisdictional question, that's right.

MR. CAMERON: Okay. Thanks, Bob, for the effort put into developing that. I don't think everybody necessarily agrees with all parts of it, obviously, but I would ask the group, for purposes of discussion, and obviously we're going to have to do this on sort of a higher level in terms of our time.

For purposes of discussion, does anybody have a problem with using Bob's taxonomy, as I'm calling it, as at least a strawman to try to discuss these various issues? It doesn't mean that this is the way you would agree to breaking these out or that qualitative goals for each of the

things that Bob mentioned, that you would agree with that.

But at least for discussion purposes, we could move through this. It gives us a useful discussion format, I think. Barbara, you had your card up.

MS. HAMRICK: It was up from a long time ago.

MR. CAMERON: Okay. But not on this.

MS. HAMRICK: No.

MR. CAMERON: Does anybody have a problem with using Bob's taxonomy? And let me ask Marty and John and Stacy in terms of from the NRC perspective, is it okay to go with this?

MR. VIRGILIO: Yes. I would have no problem with approaching it from this. What I'm struggling with now is are we in the goals or the implementing details. But I think if we approach it from a bottom-up point of view, recognizing that what we might wind up with is a goal that embraces or over-arches these areas, I think it's a good way to start. It's a very logical way to approach this.

MR. CAMERON: If you did it -- from bottom-up, you mean if you did it area by area, when you got through that exercise, you might find out that some of those were overarching.

MR. VIRGILIO: Or we may wind up with overarching

goals. Yes. We may wind up with overarching goals that would encompass those areas, but I think it's a systematic way to approach the areas we need to address.

MR. CAMERON: And, Stacy, I gather that was your -- you had basically the same comment on that that Marty did?

MS. ROSENBERG: My comment was that we seem to be getting into how to develop the safety goals and I thought what we wanted to do here was to talk about the process of how we were going to develop the safety goals and how much public input it was going to --

MR. CAMERON: That's the discussion right after this. It's the process. But I think that obviously we're not going to -- this is not the process to develop the safety goal, but I think you want to at least have a start on a discussion of that. I think we need to come back for our final discussion as to what the process is going to be.

But I think you do want to get some input on some discussion about some of the factors that would be considered in each of these areas in terms of how you might fashion a safety goal.

But you're absolutely right, the process is extremely important, process for moving forward from where

we are today. We're going to deal with that in the next topic.

John?

MR. FLACK: I think the breakdown is pretty much consistent with 99-100, except it does break out medical as a separate category.

The only question I have is the worker risk with respect to non-nuclear type accidents at process facilities and what will that mean with reactors, since we don't look at public worker risk at nuclear power plants today.

So are we setting a new goal for that arena, as well? I guess that's the question.

MR. CAMERON: When we get to that fifth category, let's hit that issue. What I really would like to be sure on now is that we can -- let's proceed to talk about these categories and anything that you might want to talk about in terms of what qualitative goals are needed, what the feasibility is. I think let's get some of these ideas out now and at least it's going to be a foundation for proceeding in the future.

The question is, it's almost 10:30. Do you want to take a break now before we begin? We're going to try and get Norman on for a little bit. We need to talk about

process, as Stacy pointed out, and I want to get sort of a summing up.

So we don't have a whole lot of time, because we need to adjourn at noon. So we're going to try to move fast and at a high level. Take a break till quarter to, Marty?

MR. VIRGILIO: Sure.

MR. CAMERON: Okay. Be back at 10:45.

[Recess.]

MR. CAMERON: One of the important issue for the NRC that we definitely need to deal with before we adjourn is what process should the NRC use to continue this look at the development of a safety goal. We also talked about process yesterday in terms of selecting areas that could be, quote, risk-informed, unquote.

We had a number of suggestions and Bob was talking about an approach, case studies. When we get to process, I'm going to ask Gary and Joe if they want to chime in about are there any lessons learned from development of the reactor safety goal that we should consider in using in process and we've already heard a lot of discussion about how that process might work and the importance of involving all of the affected interests.

One part of process is who you involved. Another

part of process is what's going to be your agenda for the next process involvement. That relates to Bob Bernero's proposed taxonomy. It may be that a next workshop could start off and devote a day and a half to discussion of this taxonomy and issues in it.

It would be the beginning of starting to develop a safety goal, but these are some of the issues connected to process. And Chia Chen suggested, for example, an external advisory committee. There's a whole bunch of things to consider.

But we need to have that discussion. But this has been a very educational experience, I think, for people around the table in terms of what we're dealing with here. We obviously don't have time to really do much in terms of discussing this taxonomy.

So I guess what I would like to do or suggest is that we might want to just briefly go through each area and get some thoughts on the table about what types of goals are needed, Bob laid some of those out, any issues of feasibility, et cetera, et cetera, and then go to process.

I'm going to ask, before we get into this, Barbara, do you have something that you want to offer here?

MS. HAMRICK: Yes. Just kind of as a preface.

Before you get to process and before you get to goals, there really needs to be some kind of consideration as to how much value there is to having national values versus local values, and the process would be totally driven by -- I mean, if local values were going to drive it, the process is going to be completely different than if an national value is going to drive it, and I'm not sure that it's this -- I'm not -- that can even be decided. That seems more like a legislative function, that decision.

MR. CAMERON: Wouldn't that be a -- if I was thinking about how to lay this process design out, I would think that one of the integral parts of having this next discussion on these areas is how national -- how the micro climates, so to speak, and the macro social policy, how those things -- I think that that needs to be thrashed out in terms of discussing these.

At this stage in time, we've raised the issue that that needs to be discussed. The next step would be -- and there may be, as Marty suggested, the national materials program working group also takes a crack at this. There may be different venues to address that issue, but I wouldn't imagine that if all of you got together and maybe a different group of people or whatever, that if you got

together to talk about safety goals in these areas, that I can't imagine that the issue that you're raising wouldn't have to be an important part of these discussions.

That's my take on it.

MS. HAMRICK: I guess my impression was kind of as we were discussing process, moving in sort of a -- you know, this would be -- it just seemed more global to me and if you're going to go in the direction of giving value to local social values, then it just doesn't seem like it would work in this forum.

I can't formulate this thought on this right now, but I do see a little bit of a problem. As long as we just keep that in mind and keep integrating that into the thought process.

MR. CAMERON: I think we have to remember that this is a -- we're doing this incrementally and we're identifying issues now that have to be considered and then we're going to be looking at what's the best process design to try to reach closure on those issues.

I think that your point has been underscored about the need to do that.

Bob?

MR. BERNERO: I feel compelled to clarify the

taxonomy presented. The process we're trying to illuminate with this workshop and this activity and the SECY paper is the use of risk information in regulating the use of nuclear materials. That's the generic process.

I made a recommendation yesterday that one needs to get into the different areas of such regulation with case studies or something like a case study as examples to illuminate the method of applying the criteria that were proposed and so forth to the use of risk information in regulating.

This safety goal statement, qualitative statement would be an integral part of each case study and it would illuminate, for instance, transportation casks, one has to face, whether or not you would have a standard off-route exposure or a local right on that.

But it's got to be part of the case study. I really think it would be fatal or certainly I didn't propose it that way, that this taxonomy, by itself, is the subject of let's develop safety goals, because I would recommend that if you want to develop safety goals, you do it in a case study, and that's where it should be done.

MR. CAMERON: I think that -- and you know, Marty or Stacy, John, amplify on this, is that the NRC went into

this workshop with -- to address two issues, and I think that your suggestion would nicely tie them together, which is what should we -- which regulatory applications should we try to use to apply risk information, risk assessment methodologies to.

The second thing was do we need safety goals, can we develop safety goals for the materials program. It may be, and this is another process question, it may be that the next time we come back is to try to combine those through the use of case studies in the specific areas. I don't know. I mean, I don't know what the best way is to do that.

But, Marty, we really had two separate, but perhaps -- well, obviously related topics on the agenda, right?

MR. VIRGILIO: Right. And we have -- I could see some merit in Bob's suggestion of tying these two together, but then we may -- well, going into it, I think we must recognize, though, that we may find a case where -- or an area where a safety goal might be appropriate, but yet given the nature of what we're regulating, that an increased use of risk information in terms of risk analysis and risk management methods may not be necessary or warranted as a result of testing it against the three criteria that we

exposed and modified through the discussions of the meeting. But it's an approach.

MR. BERNERO: What I'm saying, Chip, is the qualitative objectives are an integral part of evaluating cases to say this is how we go about using risk information and in this case, there is enough to say yes, it's a good idea; in another case, there isn't enough information to make a judgment, or in a third case, there might be enough information to say it's a bad idea.

But you would illuminate the application or use of risk information in regulating materials. That's what you're after. And then a secondary benefit, if you choose in one or more areas to pursue a general safety goal or a more specific implementation standard, fine. But you don't have to.

The thing here is how do you use risk information in regulation.

MR. CAMERON: I think the key is you don't have to do that safety goal discussion, although I think the staff was also separately interested in moving forward to see if safety goals were feasible in this area. It may be, and this gets us back to the point we talked about yesterday, about the relationship between the tools or application of

the tools and the goals.

Bob, what you're suggesting, I think, is that, well, let's go in and apply the tools to see where various areas could be made more risk-informed and that the conclusions of that application may identify areas that may be more amenable to the development or where the development of a safety goal is necessary or isn't that necessarily tied together.

MR. BERNERO: I think in some areas you're going to demonstrate that you already have a quantitative safety goal. If you go to the high level waste arena and the statement of regulatory objective, no person in future will suffer, if you go to that qualitatively, to implement that, it's called 10 CFR Part 63. So you already have it.

You regulate to a safety goal in waste disposal. That's a fact. That's a fundamental difference between waste management and reactors. You regulate to the safety goal.

MR. CAMERON: So going to your area one, waste disposal, and you talked about overall goal, no future exposure, that we wouldn't find --

MR. BERNERO: Yes. That we wouldn't accept today.

MR. CAMERON: But what you're saying now is that

we -- or what I hear you saying is that we already have a safety goal in the high level waste area and that we would not need to spend time going through a process to develop a safety goal in the waste disposal, high level waste disposal area.

MR. BERNERO: No. What I'm saying is the Commission, to my belief, does not have a qualitative statement of objective in the high level waste area, but it has an enormously complex and controversial implementation plan, called 10 CFR Part 63.

If you go into the area of high level waste, you're automatically into that, high level waste or low level waste or decommissioning waste residues, handling those, you automatically get into that idea.

But performance assessment is the measure of satisfaction of the objective.

MR. CAMERON: Although we don't -- one of the things that a bunch of discussed as we were doing agenda planning for this is to take a look at what the existing regulatory framework and the philosophy that may be expressed in there, what are the implications of that existing regulatory framework for the development, the need to develop or the feasibility of developing a safety goal.

Your example of Part 63 is probably a good example of what we were thinking about there, but I just was confused about whether you were saying we already had a safety goal there.

MR. BERNERO: Well, you've got the implementation standard for a safety goal. The Commission doesn't have the overt qualitative statement of objective. Part 61 is also.

Andy's got a whole bunch of methods for composite waste disposal performance assessment. At DOE sites, you've got a tank here and a buried crib there and whatever, and you have to take them all into account.

MR. CAMERON: But isn't it possible, though, that -- take the high level waste disposal area. We go to develop a safety goal for high level waste disposal and as people who have expressly stated or at least implied, that the process for developing that goal would have to be pretty inclusive in terms of the involvement of the various affected interests and the public in the development of that goal.

Could you indeed come up with a goal that would be inconsistent with the existing regulatory framework in Part 63? I mean, I would think that that would be a possibility. Otherwise, why the hell are we -- what are we doing? Does

that make any sense?

MR. BERNERO: Again, what is the objective of Part 63? Part 63 is very similar in structure or content to a reactor safety goal, except that it is used in direct satisfaction, in direct regulation compliance, and it's the -- all I'm suggesting is the statement of objective would illuminate that.

It's implicit. It's implicit and where it belongs is in the statement of considerations.

MR. CAMERON: So what you're saying is that we've already -- we have implicitly considered the social values and they are reflected in the existing regulatory framework.

MR. BERNERO: And there has been ample debate about whether a calculation at 10,000 years can satisfy the societal obligation versus a calculation at 100,000 years or forever, so on.

MR. CAMERON: Let's continue this sort of hybrid discussion of process and what the existing regulatory framework is in these particular areas. Go ahead, Jonathan.

MR. FORTKAMP: If that's true what you're saying, then this whole meeting is pointless, because what you're saying is that the regulation is already risk-informed.

What we need to do and I think the intention of

this is to take a step back from what's already in place, re-evaluate it from a risk-informed basis, and it may come out that the regulations don't address some of the risk-informed conclusions that we will find.

MR. CAMERON: One clarification there. I might -- you know, people around the table might agree with your conclusion, but I don't know if people would agree that just because the regulation is risk-informed, that there is a safety goal connected with it. I mean, I may be wrong about this, but I keep seeing this distinction and, Norman, you may want to chime in on this, Gary, there is a difference between risk-informing a particular area of regulation and having a safety goal for it.

Marty, do you want to add anything on that?

MR. VIRGILIO: I think maybe Part 63 may not be the best example to illuminate what we're trying to discuss here, because it is a risk-informed rule. But I think what we need to step back and look at, and Felix raised the issue earlier, there is a hierarchy of existing statements on the part of the Commission. We have strategic goals, we have performance goals, we have regulations.

Through case studies, I think we can step back and say do we have the right goal, have we stated it correctly,

do we have the subsidiary numerical objectives or do we need them, like they have in the reactor side for -- in terms of cancer risk.

Because we have, then, at the next level down, some pretty explicit requirements with regard to dose and do we have the right -- do we have the right hierarchy and have we identified all the right elements. I think case studies can take us down that path, systematically looking in areas, if you take the five areas that Bob has laid out, is one way to approach this from a process standpoint.

MR. CAMERON: Okay. Let's get some other people on the record here. Andy, and then we'll go to Barbara, and then John Flack.

MR. WALLO: A couple of things. As you're looking at waste disposal, and I'm not sure you want to go back and revisit the high level waste, as I said, you go through a risk-informed licensing process rather than a risk-informed regulation.

But I strongly disagree with Bob's statement of an objective for waste management. I think that's a misstatement that we see a lot of times, as a matter of fact, even in the international community, that no future member of the public will be exposed to anything greater

than we expect for ourselves or we don't guarantee that with performance assessments.

And rather than take a half-hour to discuss this, because this is a long issue, I would suggest one of the things is to take a look at the MAPA inter-generational study that was published a few years ago and talk about how we need to deal with future generations.

The key is here that we take steps for long-term stability. I mean, if we were going to meet that goal, we should dilute our waste and just get rid of it, just dump it out. We decided to isolate. We want to avoid catastrophic irreversible events. We want to minimize the costs to future generations. We want long-term stability. That's what we work toward. We can't guarantee that nobody in the future will be exposed to higher levels.

So I would suggest that we look at that goal carefully and I just would reference the MAPA inter-generational study.

MR. CAMERON: And this is a good -- we're using this perhaps to give examples of future processes. What you just said there, besides the substantive point itself, is that if the NRC wanted to do the next step, further explore the feasibility of safety goals in particular areas, that points like Andy's, points like Bob's would be issues that

would come up in the discussion of whether you wanted to have, whether you needed to have a safety goal there, and what that safety goal would be.

That's the type of thing that I would imagine being discussed in whatever this further process is.

Barbara?

MS. HAMRICK: I agree. I would see a lot more discussion. For one thing, just going to the primary value, as we discussed earlier, on human exposure, there are other social values that need to be factored in and this -- I don't want to harp on it, but I am from California.

There is a lot of emphasis there on ecological risks, on property damage, which it was expressly stated it should be something that should be considered, and I guess I don't see that any of that has already been sort of weighed and balanced in a public forum yet.

So to say that there already is a safety goal, there may be one, but is that the value that is going to work for everybody everywhere, and I think that part of it needs to be explored a lot more.

MR. CAMERON: John, and then we'll go to Chia Chen.

MR. FLACK: What is it we mean by regulatory

requirements and goals? I mean, regulatory requirements cause people to do certain things to meet the law. That's what they're required to do. But safety goal is a stand-back to say are we moving in the right direction based on risk. This is different.

This is not a requirement. This is what are we trying to achieve with respect to exposing the population to risk. In that light, it's something that you aspire to. You may be over-regulating, as well as under-regulating, I don't know. The case studies will be good to bear that out, but unless the case study is linked to the risk that is being exposed to the population and how much risk is the population undergoing from different areas and putting that in perspective, then you can draw the conclusion as to whether the regulation is doing what we expect it to do or maybe it's doing more than it's supposed to be doing and maybe we should back off.

But it doesn't -- I mean, the regulations, as they're written today, aren't goals. I don't see these as goals. I see these as requirements.

Now, whether we're achieving our goal and what the goal really is still needs to be articulated, and I think that's the next step. That's where we want to go. At least

that's the way I see it. I don't know.

MR. CAMERON: Okay. Thanks, John. Let's go to Dr. Chen and then over to Norman.

MR. CHEN: If you talk about the process, I think this has to be a open process. In the risk-informed regulation, I think we have two parts here. This two days, we only talk about the first part, and that's the safety goal. Now the next part is about the regulatory requirement and that's in the implementation.

I would suggest that the NRC to write up what we have talked about these two days and put in the Federal Register and solicit public comment, and I don't know whether it's necessary or not, that depends on the NRC to determine whether they need to have a public meeting or not.

And then later you have a final write the safety goal in the Federal Register. And then the second part is this, how are you going to deal with this. I think now we have five groups and I think from what I have heard, you do case studies. So you have a case study on each group and I think in the process, you have the risk there and you have all the factors, all the regulation and also you -- I think you take care of those accident exposure, and I think this also you have an open process and then you go to each one.

MR. CAMERON: Okay.

MR. CHEN: But the sense is this. You have to have an open process and get the people involved. So we don't have a -- what I have heard yesterday about a suspicion and any other thing.

MR. CAMERON: Thank you, Dr. Chen. I think everybody would agree that we need an open process. I'm going to ask, before I go to Norman, I'm going to ask Ray Johnson, who does, I think, need to leave in a few minutes.

Ray, what would you recommendations be to the NRC in terms of what's the next step in this process for risk-informed regulation and/or development of safety goals? What would you recommend to us? Should there be further workshops, what agenda items?

MR. JOHNSON: What I think would be helpful, and I think a lot of work has already been done, and I had raised this as a question yesterday, which is do we know what the risks are for different applications of nuclear materials in order that we can actually inform workers or the public about those risks.

My question was raised in this regard that as a concern for those who are implementing regulatory requirements, which I've mentioned and others have that they

are becoming or have become quite prescriptive, the question arises on prescriptive requirements as to what is the risk associated with those requirements.

In other words, why are we doing some of the things that we're doing, this is a question that I get asked all the time, why are we doing this.

I'd like to be able to say because here is the connection with risk that we're averting by this action, and I can't do that now. There are things that we're doing that I can't clearly identify the risk basis. So my interest is can we establish what the risks are for different activities involving nuclear materials as a basis for informing workers and the public, and relating that to the current requirements for implementing regulatory programs, such that we can identify the risk basis.

MR. CAMERON: So you would suggest that the NRC, at least initially, would go off by itself perhaps and apply some of these risk assessment methodologies to determine what the actual risk was and then perhaps propose changes to its regulations based on that.

MR. JOHNSON: Well, I think so. Yesterday, I was asking some questions of Marty here on the -- Scientech has done a study on risks from various systems or categories of

use of radioactive materials, nuclear materials, and what has become of the output of that study.

What I've heard is that already some of the output of that has factored into priorities for regulatory inspections. So that in other words, risk information already apparently is being used, but I don't know that that information is widely available or appreciated or understood.

MR. CAMERON: Marty?

MR. VIRGILIO: I just wanted to make sure the record is straight on that. What we have now is published that study. There's a Commission paper associated with it and, unfortunately, I don't remember the number, offhand.

One of the things that it's telling us, one of the insights you get from that is that the priorities that we have established for some of the materials inspections might not be the right priorities, but we haven't initiated any changes yet. We're still exploring that further.

One of the things that we're going to be exploring with the ACNW/ACRS next week, when we have the workshop with them, is where do we go with this study. There's a lot of, I think, information, good information included in that study. There are a lot of areas it has identified, I think,

where we have uncertainties, where maybe additional study would be helpful to make decisions, and I think there are areas where we could make some decisions based on the results of the study that we have.

But I think it's to come and further discussion will be held next week.

MR. CAMERON: That SECY number is 00-0048, nuclear byproduct material risk review.

MR. VIRGILIO: Thank you, Chip.

MR. CAMERON: And it's about 3,000 pages, or if we want to do it in pounds, it's, I think, about 15 pounds.

MR. FLACK: Chip, just for the record, that's NUREG/CR 6642, if you just want to get the NUREG on that.

MR. CAMERON: That's the underlying Scientech study. The SECY paper was 00, as in the year 2000, 0048.

I want to get Norman on and then I want to ask Gary if he has any recommendations from the experiences of the reactor people in terms of -- and what he's heard today and yesterday in terms of what process the NRC might use in moving forward on one or both of these issues, these issues being how to further use risk information in various regulatory areas, what safety goals to develop.

Then I want to get ideas from all of you around

the table on that same issue.

Norman?

MR. EISENBERG: My premise, and I believe it's the premise in SECY 99-100, is that the reactor approach to safety goals is not -- cannot be duplicated in the materials area. You have a mixed bag in the materials area. In some cases, the regulations are very prescriptive and have very little risk insights incorporated into them, and in other cases, as Mr. Bernero has pointed out in the high level waste area, compliance is demonstrated with a risk assessment, with a performance assessment.

Well, when you have that situation, you have -- I agree with Bernero -- you have articulated what the safety goal is for that particular area of regulation. So because there is a mixed bag, I don't think you can generalize one way or the other that you need to set them up or that you can derive them from the regulations.

I think some regulations and maybe accident or risk from sealed sources might be a good example, I don't think there is a statement of a safety goal for what level of risk is tolerable in that particular area.

But in the waste business, I think you're there already. You have articulated the overall objective for the

regulation, as well as the specific quantitative safety goal in the regulation.

MR. CAMERON: Okay. Thank you on that, Norman. Bob, do you want to comment on that, on the larger issue?

MR. BERNERO: I would like to comment on that and also to Andy. The essence of the problem, in my view, is that the 10 CFR 63, the performance assessment is setting terms of compliance in a fashion that is not consistent with the qualitative statement of the safety goal that I suggest. And it ties into a -- I believe Andy used the word demonstrating.

People sometimes say proving even. That is the difficulty. The objective is or goal is that no one in future will receive. Recognizing what the MAPA study did is the strategy for managing waste is to contain it and not to dissipate it and then one needs a reference to say to what extent should it be isolated and it's that statement of extent that I regularly encounter in discussions of Part 63, and I heard this not long ago, that the NRC's interpretation of Part 63 and the explicit use of terms is that for purposes of hearing litigation, it must be demonstrated that the exposure is less than 25 millirem a year to the average member of the critical population group in the Amergosa

Valley.

It has all the strong flavor of proving. It is not a risk assessment. It's a compliance assessment, and that's the curse. The curse in regulating to a safety goal is when you go to a future risk assessment and convert into a compliance assessment.

I'm confident that not now and not ten years from now, if I'm still here, will I see clear demonstration that Yucca Mountain has exposure mean value less than whether 25 millirem a year or 15 millirem a year or four millirem a year. That's really not the crucial thing. It's proof. There is no proof and there won't be proof. It is a risk assessment.

And what is lacking is a statement of qualitative objective, what is the regulatory strategy and objective, and then is there room for quantitative demonstration or implementation of that and it's already a foregone conclusion that in waste management you will have it.

You have it in Part 61, you have it for decommissioning, and you have all the bells and whistles of how do you demonstrate that.

And that's the crucial thing, it's a risk assessment that I think is converted into a compliance

assessment and it guarantees that you won't exceed a licensable value. To me, societally, that is foolish.

MR. CAMERON: Thanks for that clarification, Bob, on the high level waste area. I'm going to ask Gary if he has any thoughts for Marty and John, at least for the next week, and Stacy, for how to move forward in terms of putting a finer point on the issues that we've been discussing for the last day and a half.

MR. HOLAHAN: I do have a few recommendations. My first recommendation is don't make recommendations without thinking about them for a while. But I'm going to violate that first recommendation by giving you my instant analysis.

My recommendation would be to pursue risk-informed regulation and safety goals in parallel and not to do one first and then the other, because I think they both take a long time and you learn something by what I would say is the analytical approach.

In other words, do the risk analysis and see how well those risks are dealt with in your regulations and also be more philosophical and see whether your values are being well served by those requirements.

I would do them both in the hope that ultimately they will converge in some way, but maybe in a way that you

can't quite see it at the moment.

Process-wise, I would suggest that you start out by taking the results of this workshop, summarizing them, letting the Commission know what's going on, putting the transcript and other thoughts from this meeting out for comment.

I think it's the staff's obligation to move the issue forward and I would say to draw some conclusions from the meeting. One of the conclusions I would draw is that it is worthwhile to pursue the issue of developing safety goals, that we probably don't need a single safety goal, but maybe a series of those; to suggest that thought as part of putting the transcript and the meeting notes out for comment to see whether people react well to that or will they think that fact is not reflective of what was going on, or people who weren't here can add their thoughts, under the presumption that there would be some positive reaction to that.

I would think you would want to set up maybe a series of workshops and meetings, because I think these issues are just too difficult to deal with in a day and a half.

I think there are different stakeholders between

high level waste and medical applications, that it would be helpful to take the categories. And Bob's categories are as good as any to start and I also agree with Marty that eventually you may find out that there are enough commonalties that they converge at some point or that they have to split off and that you end up with six instead of four or five, whatever. But starting with those categories are as good as any.

I would do those with the goal of writing down a first draft of a safety goal in each of those areas and then floating that out for public comment, and end up going through that process with a recognition that it might take you years.

I wrote down five years, but you can say -- pick any number you want. I think it would take you years to develop a coherent set of thoughts or hopefully some consensus on those issues.

And then ultimately, when you have something that you think reflects your safety goals, I would put them in the strategic document in a more general section or an introductory sort of section that explains in general terms what it is you're trying to achieve, why the strategic goals are what they are, and how you intend to have your

regulations and other regulatory programs measured against those objectives, and then what sort of program you have for doing corrective actions.

In other words, you're doing this process because you want better regulations, better regulatory programs. So you need to be prepared to change your programs to better meet your objectives.

It seems to me that the second reason you're doing all of this is to explain to people better why your programs are what they are and what they're trying to achieve. So you've got to write them down in some place where people can read them and hopefully agree with you, but even if they don't agree with you, at least they have a better understanding of what you're trying to achieve.

I would tell the Commission that the staff thinks this is a reasonable thing to do and make sure the Commission wants it done.

MR. CAMERON: Thank you, Gary. That sounds like -- let me ask and get the reactions of other people to that. Just one clarification. This series of workshops would be -- it could be done incrementally. You could revisit the subject generally with all of the various categories.

You could do breakout groups perhaps by category,

if you want. You could continue, you would need to, and Gary is really emphasizing a long-term process here, where you might do one workshop that had some breakout sessions, but overall consideration.

Then you might do workshops category by category, different sets of people involved. That's within your contemplation, I guess, right?

MR. HOLAHAN: Yes. As a matter of fact, I would suggest you pick the easiest topic for which you can achieve the most success quickly to convince people that this is actually a worthwhile thing to do, it's something easy.

MR. CAMERON: Thank you. I'm going to go to Chia Chen and Dr. Lull. Let me ask Barbara for her take on what Gary suggested, and let me ask Felix for his take. Barbara?

MS. HAMRICK: I guess, once again, I can see, in the series of workshops, that not only might you want to divide it up by category, but you would want to be sure to spread yourself around the country and get the local input and get the feeling of what's important to people, because it seems like we're still all talking about one value here and I have the concern, just in general, that that value needs to be expressly stated.

If NRC's ultimate safety goal is just to look at

human exposure, then somewhere that needs to be -- just come right out and say that, because that is not the sole value for all the stakeholders, in my opinion.

So I would just say that geographically, those workshops really need to be spread out.

MR. CAMERON: That's an excellent, appears to be an excellent suggestion, and it just highlights, I think, something that I'm inferring from what Gary said, is that this is going to be a long and involved process and that one of the things in terms of next steps for the staff is to perhaps inform the Commission of their plans and that this might be a long, involved process.

Because if you're going to do the series of workshops and then you factor in the regionality aspect, which I think is good, then it is going to be later rather than sooner. Felix?

MR. KILLAR: I certainly don't have any problem with what Gary suggested. I think the biggest issue that I see from my members and stuff and talking to them about this workshop is that they're looking for more focus.

I think that if you do these, you need to do them possibly by maybe these five categories or six categories that Bob has provided, because then it would have more

meaning for the particular licensees and their participation and stuff.

I think maybe if you establish sort of the -- and you could go two ways, maybe as Marty suggested, that you start with the individual ones and then after you get all the individual ones done, you say, well, gee, can we -- for these five individual or six individual categories, can we come up with an overall umbrella type safety goal versus trying to come up with an overall safety goal and try and force it down.

But I think certainly you need more focus for these things to go forward.

MR. CAMERON: Thank you. I think that that would be the goal, is to continue to get more focused with each step. Let's go to Bob and Jonathan and Dr. Chen and come back to John Karhnak, and then I will poll the rest of you. Dr. Lull?

MR. LULL: I really strongly support this idea of breaking them out and bringing people together. I would request that when you look at risk-informed approach to regulations, that, at the same time, you look at risk-informed approach to how you can modify the regulation enforcement or inspection process and that that can make a

really big difference also and that's -- and I can see like in the medical area, there are many changes that could be made on that basis that would improve the life of everybody and make life a lot easier.

So I would hope that you would consider that a hand-in-glove kind of relationship. I would suggest that perhaps medical might be one of the areas where there is actual activity going on all the time, that might be an approach that you might want to look at early, perhaps industrial use also might be something that would be helpful.

MR. CAMERON: Thank you. I keep thinking about you and your bigger and better suit, radiation protection suit.

MR. LULL: That wasn't my idea.

MR. CAMERON: Jonathan.

FORTKAMP: I think it's a good approach, as well, what Gary has established, I think, in general. My thoughts as well for he suggested coming up with some draft safety goals and I thought perhaps would it be possible to take the regulations as they exist today, the statements of considerations and other documents associated with the development of the goals, and from those pull out the safety

goals for the regulations as they exist today, as a way for a first draft of safety goals, saying this is where we are now, this is -- you know, they've never been --

Obviously, they've never been clearly defined as such, but I think there's a fair consensus that they're somewhere nestled in the regulations and the development of the regulations, there were some safety goals. And if we can pull those out of the regulations as they stand now, that would be a good starting point, a good first draft of the safety goals for the areas defined.

MR. CAMERON: At a minimum, I think what you may be suggesting is that as background information for the participants in this workshop, that the NRC staff pull together a cut at that, that would be sort of the foundation information that people would get for preparing for the workshop.

MR. FORTKAMP: I would also like to state that the regional meetings are going to be important and I think that's going to be most important, because I firmly believe that in order for these to be successfully implemented in the materials side, they have to be consistent across the NRC and all agreement states.

I don't think you can have regional

inconsistencies because of the interstate commerce aspects of a lot of these material licensees, be it just transportation between it or be it a manufacturing and distribution into and out of various states.

I think these have to be consistent across the board and in order to do that, you need to get the regional inputs.

MR. CAMERON: Again, I think that whether the necessary amount of consistency versus allowing states to recognize individual differences is going to have to be an integral issue that's discussed in those particular workshops. It may different, obviously, from category to category.

John Karhnak and then Chia Chen.

MR. KARHNAK: For the last hour or so, we've been having a very nice orderly discussion as if we could just kind of move this thing one down step after step, and I'd just like to remind you that we really need to come to grips with some of the issues that Amy and Judith brought up yesterday and either decide that you're going to do something to come to some sort of resolution with them or make a conscious decision that you cannot come to a resolution and you're going to go forward without them.

They brought up some things and when I hear words like never and always, it leads me to believe that there is going to be a great deal of difficulty in trying to come to some sort of a resolution. We couldn't even get the word unnecessary into the discussion of regulation yesterday.

As soon as reducing regulation came together, the unnecessary disappeared from the discussion. Somehow or another, we have to get around the point of just automatically saying no to everything and getting some discussion about -- and perhaps ultimately disagreement, but nonetheless, at least come to the discussion of what's really on the table in the full context of what's on the table.

MR. CAMERON: Excellent point, John, and I guess my assumption from what people have been saying is that that issue would have to be dealt with directly head on in these processes. There is no way around that and it may ultimately come to disagreement and it may be very difficult to move forward, but it has to be dealt with squarely in these processes that we're talking about.

Let me ask one point, to make sure that we're clear. First, one of the first points that Gary said is that pursue risk-informed regulation and safety goal in

parallel, first of all, not in sequence. And then Gary laid out a process for mainly focusing on the safety goal aspect of this.

So keep in mind that there is still the issue of a separate process piece perhaps for the risk-informed regulation part of it, unless somehow you can marry those things together, and I just want everybody to be clear what we're talking about here. Chia Chen?

MR. CHEN: This you just talked about is about my concern about. I think we should have a safety goal first, because safety goal itself is guideline for what you're going to do in the five groups. After that, then the five groups can go simultaneously, and I would suggest that when you go to each group, that NRC could have some proposal for that.

The reason I say you put in the Federal Register is this. No matter if you are proposal or your final, you don't have a preamble and I think actually -- the sense of my suggestion actually is to deal with reaction I have seen yesterday from Amy and Judith.

The easy to convince public is this, it's two ways. One is you have public meeting and then you -- everything has a record there and your final is based on the

record.

I think it the preamble there is what would convince pieces. Thank you.

MR. CAMERON: Thanks, Dr. Chen. Marty, you have a comment?

MR. VIRGILIO: I'd just like to respond to that comment, because I believe there is a lot of benefit in the parallel approach. I believe that absent safety goals, we can use risk information to do things like Bob suggested, go back and look at inspection and enforcement within current regulations and make some decisions.

The example I cited was using the material risk review group report, what we're starting to see is some insights that are telling us that maybe our inspection priorities aren't right, that maybe we're inspecting some licensees too frequently and others not frequently enough.

That's the kind of things that we can do today, even before we have the safety goals fully developed. I think the NRC ought to move forward and make those changes where it can today, and that's why I favor the parallel process.

MR. CAMERON: Okay. Thank you, Marty. Mike, any comments on process? Andy?

MR. WALLO: I guess I would say as you start through this process, certainly use your criteria to decide how you're going to do your -- what do you call them -- case studies. Select something that you can do and I guess I would add one more, since we talked about the relationship of doing this process and what impact you might have on high level regulation, is you need to add a criteria that says the time criticality.

You don't want to get involved in a case study that's going to somehow mess up some issue you have that's time critical, because I agree with Dr. Holahan that you have probably a long road to haul here to get down some of these.

So you might do your case studies on things that you don't think are time critical.

The last point is, I know Bob will get another shot, but I still disagree with his general waste management principal. It is not a good one.

MR. CAMERON: Who is going to get the last word here?

MR. WALLO: I think he's got it.

MR. CAMERON: I won't call on him again.

MR. WALLO: Okay, good, good.

MR. CAMERON: You're off, Bernero. No. But I think that point that you've made is also something, if we did a workshop on a particular one of these categories, is that one of the factors in terms of going forward would be this issue that Andy brought up perhaps.

So there's different ways to factor that in. let me hear from Norman. Do you have any thoughts on process? I just want to make sure I get everybody on process.

MR. EISENBERG: Just perhaps I should save it for if we're going to go through -- or maybe we're not going to go through general comments.

But I would think --

MR. CAMERON: We will, quickly.

MR. EISENBERG: But I would hope that advantage will be taken of the information that's already been obtained for a wide variety of risk studies, that the staff should pay attention to those and if they're going to hold a series of workshops, make sure that they bring forward that information to help facilitate the discussions.

MR. CAMERON: And that supports some of the things that we've heard about the staff preparing the necessary background information and material to allow these workshops to proceed more efficiently.

Let's give John -- John, do you want to say something? Let's give people a chance around the table to make some general comments based on what they've heard over the past couple days. I do want to go out and see if anybody in the audience has something to say on it.

Do you have something on process?

MR. ORVIS: I do have something, but I'm not sure if it's process or not.

MR. CAMERON: Okay. Why don't you go ahead? Please identify yourself for the record.

MR. ORVIS: My name is Doug Orvis. I'm here as a private citizen, but I'm currently employed with the Yucca Mountain project. I'm involved with the pre-closure safety, which hasn't really been talked about much. It's one of the sub-categories.

But we are working to Part 63, which is risk-informed, and in some of our -- the thing I really want to bring up, as you go through trying to think of ways to apply risk-informed through reduction inspections or quality assurance and the graded quality assurance, is some issues that we have been having dialogue with the staff recently.

We have gone through a PRA kind of approach to

meet the regulations, but as we started to get into graded QA, questions came up about what is your risk measure and trying to apply the Reg Guide 1.174/176 to delta risk, and that is a problem.

So as you try to develop this parallel approach, you may want to think of how you're going to have risk-informed reduction of regulations or how you're going to apply those. I'm not sure if I'm saying it clearly, but there is not a single quantitative risk number that we start with and look at delta risk. So it has to be an intelligent approach, obviously. There are ways we don't want to take the whole nine yards for everything.

MR. CAMERON: Thank you, Doug. I think we've heard some expressions of that and that sort of ties in with what you just said, Marty.

Joe Murphy.

MR. MURPHY: I'd like to make a couple of points. I'd like to second what Gary has said, in general. I think if you take the combination of what Marty and Norman both said, you have a real advantage.

You can go forward with risk-informing regulations based on the information you already have and the information you're gaining as you go along. What you will

find, at least what we found in the reactor end is that you will find that there are areas where you are placing much too much emphasis in some areas and not enough in others.

You will find areas, at least we found in reactors, something that, in his more elegant days, Bob Bernero referred to as gaps in the fabric of regulation. I remember that term, even if you don't, Bob.

That indicates that when you find such a gap, that you need to fill it. So it's a two-edged sword when you gain useful information.

I would suggest that as you go forward, you remember there is an advantage in the reactor space that may be disappearing from the discussions I have heard here, and that is the difference between goals and requirements.

Goals, to me, are something you strive for. Requirements or regulations are something that you're required to do by definition. I would not set my goals where the regulations are. I would set my goals lower.

I would say I should strive for a higher level of safety, if you will, and that's sort of an ALARA principal. But I would be satisfied and feel I had provided adequate protection for the public and the workers at a different level than that, and having those two constructs allows you

to use cost-benefit analysis, allows you to have room for exemptions from regulations. It allows you a lot of leeway that may not be obvious at first glance.

I would urge you to think about that. I would urge you, as you go forward, to follow up on what Barbara has said. I think you need, besides the taxonomy that Bob mentioned, perhaps a taxonomy that splits this into a matrix that says you will consider things like operational risks, accidental risks, ecological risks, perhaps something like diversion of material risks.

These may be different as you go from application to application. In some cases, you may need them; in some cases, not. But I don't think you can forget them. You have to have a logical basis for how you go forward with them and some may take more time than others and for that reason, I would urge you to take somewhat smaller steps as you go along to develop these things.

And just from past experience, on the reactor end, where it took us from roughly 1970 to 1986 to get safety goals out, we really got the basic idea that we needed them after TMI, which was in '79 or '80, we started, and then in '86, the first publication came out.

And we really didn't get good firm guidance as to

what to do with them after we got them, until the SRM that Gary mentioned came out in 1990 from the Commission.

So it's a long process and keeping the Commission involved early and letting them know the steps you're taking, I think, are important.

Finally, I would like to second the idea that I heard earlier that you start off trying to develop clearly what your objectives are and from the objective, let that flow towards qualitative goals. You may well find in each of these four areas that I discussed, and you may find, at that point, you don't need to go any further, but in some places you may.

But I would always try to keep this difference. I see there has been a real advantage in reactor space to have a difference between requirements and goals and I sense, from a lot of the discussions that are going on today, that we tend to be mushing them together and I'm not sure that that's the most advantageous thing.

MR. CAMERON: Thank you very much. I know that you didn't mean to suggest by using the phrase Bernero in his more elegant days that he's not still elegant, even though Andy disagrees with him about something.

Mike, let's go to you, and then go to Bob, and

around that way, counter-clockwise, for any final comments that any of you might want to offer.

MR. WANGLER: Thanks, Chip. I'll try to make it brief. I personally like what I have heard discussed over the last two days, day and a half. I think that it's an appropriate way to go, although -- and I've been doing -- working in the regulatory arena for a lot of years, New York State, NRC, DOT, DOE.

I think that there was an implicit consideration of risk in the rule-makings that I worked on. If not an explicit one, I think that the process that you're going through here will make the use of risk more explicit than maybe what I perceive has been used in the past.

I think the NRC is going to have its job cut out for it in developing the process and getting it to work the way they want to. There are a lot of areas, as we've seen here, that NMSS has to cover and they're not all going to have the same goals, at least in the development of the goals.

I think NRC is going to have to be pretty explicit in how it uses risk. Risk, some of the elements of risk that were mentioned include consequence and probability, whether both of them can be used simultaneously, individual,

that's going to be have to be worked into the process, I think, and some of that is in the information that we've had before.

You're going to need to -- it's been said before, you're going to need to get the right people involved or at least try to get the right people involved and get them to discussing the process with you. It's so much easier to get people to buy into a process if they have participated in the development of the process than it is after the fact.

I won't speak for Andy, but certainly for my program, the transportation program, if there is anything that we can do to participate in these kinds of fora or directly participate in working groups that the NRC has for the development of a risk-informed approach to the regulatory process, I'm volunteering at least for my program to participate in those.

MR. CAMERON: Thank you very much, Mike. Bob?

MR. BERNERO: I don't know if Andy should volunteer, because he's often wrong. But seriously --

MR. CAMERON: He's next, he's further down the road, so he's going to get you.

MR. BERNERO: The workshop, I believe, has been very helpful and much of the summary advice by Gary and Joe

that we just heard is good advice, and especially with regard to biting off pieces that are manageable. You know, pick the low hanging fruit, you will make more progress that way.

I would urge that there be a sharp focus on the purpose of this that it is developing criteria, standards and practices associated with risk-informing the regulatory process in NMSS, and that can sometimes be lost if you start going too deep or dwelling too long on one particular safety goal.

And the only other observation I would like to offer from past experience, I would suggest that if you go into the statements of considerations for all the regulations and other published literature, you will find precious little that is useful as the basis for safety and safety goals.

All you have to do, go in the reactor area and the years and years of strife about how do you define whether a component is important to safety. And in 10 CFR 72, 20 years ago, we wrote in 72.3, which was a definition of important to safety that is still difficult to work with today.

MR. CAMERON: Thank you very much, Bob. Felix?

MR. KILLAR: I think Bob said it all.

MR. CAMERON: All right. Marty?

MR. VIRGILIO: I would like to take this opportunity to thank Stacy for setting up this workshop and, Chip, for you and your efforts not only to facilitate this, but to convene this group of people who have more than once throughout this process "aha'd" me with new ideas of how to proceed in this area. I really thank you all for your participation. It's been very helpful.

MR. CAMERON: Bob?

MR. LULL: First of all, I want to say how honored I am to be at the table with all of you. I've learned a lot from each one of you and hopefully I can take this back to my medical community and enlighten them on this.

You know, we in medicine have felt that we've been pretty over-regulated relative to the historical risks associated with it and we're kind of unhappy with the results of the most recent effort to try and apply risk assessment and risk-informed approach to medical regulation.

I'm hoping that perhaps by pursuing this, and I'm very happy that there is pursuit of risk analysis and risk-informed approach, that we can achieve easier operational characteristics, less burden on the NRC staff,

and still accomplish the same safety goals, which are undefined, but will be defined.

I would suggest that when we're defining and looking at safety goals in each of these segments as this evolves, if this does evolve, which I think ought to, that it will be a matter of deciding which levels and how much you divide things up. For instance, as I pointed out earlier, medical -- well, both medical use, nuclear medicine and radiation therapy consider themselves extremely distinct, just as distinct in a sense in terms of the risks and the application of regulation requirements to them as, for instance, low level waste versus high level waste, even though they're both the waste issue.

So within each of these topics, there will be distinctions that will have impacts, and that's why you need to bring people in who can discuss those and help resolve those distinctions.

In any case, thank you very much. I've really enjoyed it.

MR. CAMERON: And thank you for coming out from San Francisco to join us. Chia Chen?

MR. CHEN: I enjoyed the chance to meet all you these two days meeting and I think I have said all I need to

say, but I would like just to mention one little thing.

I would like to suggest that NRC probably change the workshop to a public meeting.

Thank you.

MR. CAMERON: It is a public meeting.

MR. CHEN: But change the word workshop.

MR. CAMERON: All right. Thank you, Chia Chen. Gary?

MR. HOLAHAN: I'd like to thank Marty and Stacy and John and others for inviting me and for the opportunity to talk about something that the general subject I'm interested in, in an area for which I know not much.

From all I've heard yesterday afternoon and today, I think this is a good start. I think it's a worthwhile effort. One thing that's clear is that there is a lot of work to do and it seems to me that there's a lot more participation that needs to be worked on, as well.

Even if you look around the table, you see that there are a lot of different communities represented. There are also a lot of communities not represented and I think some mechanism for dealing with that will be important to this whole effort.

MR. CAMERON: Thank you, Gary. I know we would

all thank you for providing the foundation for our discussion. Stacy?

MS. ROSENBERG: I also wanted to thank everybody. This has been very educational for me. I agree with all of the discussion on the process. I think that's a good way to proceed.

I think it's going to be a very big job for the NRC to go back and state what's implicit, what's the implicit safety philosophy in the existing regulations. I think that's going to be a very big job.

And I just wanted to point out that I think that communication is very important in these meetings and that even that we need to educate the public as to what we believe the risks are. But we also need to be educated by the public as to what their values are, as well. I think that's a very important point.

MR. CAMERON: Thank you, Stacy. Barbara?

MS. HAMRICK: I just wanted to say I think this was very valuable, too, and I hope that the proceedings are published, because I would like to encourage the other agreement state program directors, and the staff, as well, to take a look at what the NRC is doing and to become involved in the process, so that you'll get a lot of

participation when you go out and do the workshops.

MR. CAMERON: Thank you, Barbara, for not only your comments, but also for coming a long way to join us. Andy?

MR. WALLO: I want to thank everybody, too. We've found this very useful. It's been some time I've been trying to keep up with the Commission's work in this area and I think this was very helpful in catching me up.

The only other general comment I would make is I guess as we look at management and risk management, that focus on the need also, while you want to set goals that are out there and you have to reach for them, they need to be achievable.

You don't want to set goals that clearly are not achievable, that doesn't work real well, and particularly in the area of separating between your qualitative and your quantitative goals.

I think one of the suggestions was a qualitative goal, like do more good than harm or don't do more harm than good, hopefully we would always achieve that goal if we set a qualitative goal like that.

That's the only comment I would make.

MR. CAMERON: Aren't you forgetting something that

perhaps Bernero was wrong?

MR. WALLO: I thought that went without saying.

MR. CAMERON: John?

MR. FLACK: Again, thanks all around. I think the objectives of the workshop have been met, and that was to inform stakeholders about what we intend to do and to get input into what we're doing, and it sounds like what we're doing is worthwhile and I think that was really one of the objectives of the workshop.

It's going to be a long process, there's no question about that. I think the case studies, I see the case studies as almost like WASH-1400 and the PRAs that we did in developing the safety goals and in this case, we're really coming to grips with that, having to go back, do case studies, find out exactly what is the risk, and be satisfied with that, and not set goals that are not achievable, but goals that are realistic based on those studies.

Again, even with the goals, it's not that we regulate to them, but we use them to guide our regulations, but we still have regulations that need to be met and I think that's true and we shouldn't lose sight of that.

But overall, I thought this was extremely useful for the process and hope to be working again with everyone

in pursuit of these goals.

Thank you.

MR. CAMERON: Thanks, John. Jonathan?

MR. FORTKAMP: I, as well, think that we're heading in an appropriate direction here. It's apparent that risk -- obviously, risk information has been used in the development of most, if not all of the rules, to some extent, but I think it's important to establish a consistent process for application of the risk information and the development of the regulations, licenses, license review and inspections.

This has been a nice forum, but I have to admit I feel a little lost in it. It's kind of just a little licensee, a lot of the talk is at a much higher level than you get down to just a gauge user.

I think it's important as we go out into the communities that we get a lot of licensee participation and from the broad spectrum of licensees that NMSS encompasses.

I would like to, as well, thank you for inviting me to this, and hopefully I've contributed something.

MR. CAMERON: Yes, you have and thank you for being here, Jonathan. Norman?

MR. EISENBERG: There were some comments made

yesterday that maybe were never fully responded to, and maybe this would be a good time to just state that the goal of the regulation is to provide for safety.

The reason to do risk assessment is that it's a systematic scrutable approach that is very useful because it lays out what is known and what is not known and articulates the uncertainties which then the decision-makers, which includes all the stakeholders and the public, can use to weigh in their decision and decide how much weight to give the technical analysis.

I think this idea that the risk assessment goes on as a technical analysis separated and driving decisions is not correct, that it's an adjunct to decision-making, an important adjunct and something that can be quite helpful.

So I thought that would -- that's an important point to make.

MR. CAMERON: Thanks for putting that on the record, Norman. Anybody else out in the audience want to say anything before we adjourn the workshop?

Okay. Well, I would just thank all of you and have safe travel home. I'm sure that we'll see you again in a venue similar to this.

[Whereupon, at 12:18 p.m., the workshop was

concluded.]